Supreme Court, U.S.
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No. _____

In The
Supreme Court of the United States
October Term, 1997

IN RE: SOFAMOR DANEK GROUP, INC,

BRUCE G. MURPHY; RANDY OWEN;
MARY KENNEDY; AND LYNDA KRAMER,
Petitioners,

v.

SOFAMOR DANEK GROUP, INC.; ET AL.,
Respondents.

Petition For A Writ Of Certiorari To The United States Court of Appeals For The Sixth Circuit

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PETITION FOR WRIT OF CERTIORARI
with Appendix

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178 pp

QUESTIONS PRESENTED

1. Must this Court reverse and remand for the plain error of the courts below, which in dismissing this suit completely ignored and failed to consider a claim stated in the complaint for violation of the federal securities laws based on the clear and undisputed *affirmative misrepresentations* of the defendants (as opposed to a claim based on omissions)?

2. Under the federal securities laws, must a company disclose to the investing public material activities in which it is clearly and undeniably engaged which place it in clear jeopardy of serious and damaging negative consequences, such as severe and possibly crippling civil, administrative or even criminal sanctions, particularly once the company has voluntarily chosen to speak on the subject, denying that it is engaged in any such activities?

PARTIES TO THE PROCEEDING

Petitioners Bruce G. Murphy, Randy Owen, Mary Kennedy and Lynda Kramer each appeared as Plaintiffs-Appellants in the Sixth Circuit proceeding. Sofamor Danek Group, Inc., E. Ron Pickard, Laurence Y. Fairey, Leander D. Beard, George F. Rapp, Miles D. Igo, Alan J. Olsen, Yves Paul Cotrel and Phillipe Cotrel each appeared as Defendants-Appellees before the Sixth Circuit.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i
PARTIES TO THE PROCEEDING ii
TABLE OF AUTHORITIES vi
OPINIONS BELOW 1
JURISDICTION 1
STATUTES AND RULES INVOLVED 2
STATEMENT OF THE CASE 4
REASONS FOR GRANTING THE WRIT 12

I. The decisions below are plainly erroneous and manifestly unjust, as the courts below simply *ignored* and *never considered* the clearly viable claim stated in the complaint for violation of the federal securities laws based on the defendants' untrue statements of material fact, which claim was based on clear and undisputed *affirmative misrepresentations* made by the defendants 12

II. When a company is engaged in activities which place it and its investors in clear jeopardy of serious and damaging negative consequences, such as severe and possibly crippling civil, administrative or even criminal sanctions, the federal securities laws mandate, under the basic tenet of complete and accurate disclosure, that the company disclose the activities; this is particularly true once the company has

denying that it is engaged in any such activities. As such, the Court should grant this petition and issue the writ requested in order to reverse the opinion below which, through its misapplication of applicable law, is clearly erroneous and in stark contrast to the fundamental principles and purposes of the federal securities law 14

CONCLUSION 17

APPENDIX

Appendix A

Final Sixth Circuit Court Opinion,
filed 8/14/97 . . . . . A1-A28

Appendix B

Sixth Circuit Court Order Denying Petition For Rehearing and Suggestion For Rehearing *En Banc*,
filed 10/9/97 . . . . . B1-B2

Appendix C

Order on Defendants' Motion to Dismiss,
filed 10/3/95 . . . . . C1-C35

Appendix D

Judgment,
filed 11/6/95 . . . . . D1-D4

Appendix E

Appendix E

Petition For Rehearing and Suggestion For Rehearing *En Banc*, filed 8/28/97 ..... E1-E17

Appendix F

Consolidated Amended Complaint, filed 9/2/94 ..... F1-F62

TABLE OF AUTHORITIES

Statutes: *Page:*

15 U.S.C. § 78j(b) 2,10

15 U.S.C. § 78t(a) 10

28 U.S.C. § 1254(l) 1

Cases: *Page:*

Basic, Inc. v. Levinson, 485 U.S. 224 (1988) . . . 15, 18

First Virginia Bankshares v. Benson, 559 F.2d 1307 (5th Cir. 1977), *cert. denied*, 435 U.S. 952 (1978) 15

In re Carnation Co., Exchange Act Release No. 22214, 33 SEC Docket 1025 (1985) 18

In re Par Pharm., Inc. Sec. Litig., 733 F. Supp. 668 (S.D.N.Y. 1990) 16

Santa Fe Indus. v. Green, 430 U.S. 462 (1977) 16

SEC v. Capital Gains Research Bureau, Inc., 375 U.S. 180 (1963) 16-17

SEC v. Texas Gulf Sulphur Co., 401 F.2d 833 (2d Cir. 1968) (*en banc*), *cert. denied sub nom., Coates v. SEC*, 394

U.S. 976 (1969) 12

Rules and regulations: *Page:*

17 C.F.R. § 240.10b-5 (SEC Rule 10b-5) ..... *passim*

Supreme Court Rule 13.1 1

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Sixth Circuit that gives rise to this petition, reported at 123 F.3d 394 (6th Cir. 1997), is reproduced in the petitioners' appendix at A1-28. The order of the United States Court of Appeals for the Sixth Circuit denying petitioners' petition for rehearing and suggestion for rehearing *en banc* is reproduced in petitioners' appendix at B1-2.

JURISDICTION

The judgment of the Court of Appeals was entered on August 14, 1997. See Appendix at A1-28. Petitioners filed a timely petition for rehearing and suggestion for rehearing *en banc* on August 28, 1997, see Appendix at E1-17, which was denied by the Court of Appeals on October 9, 1997. See Appendix at B1-2. Pursuant to Supreme Court Rule 13.1, this petition has been filed within 90 days of the denial of rehearing. This Court has jurisdiction under 28 U.S.C. § 1254(l).

STATUTES AND RULES INVOLVED IN THIS CASE

Section 10(b) of the Securities and Exchange Act of 1934, 15 U.S.C. § 78j(b) provides:

> **78j. Manipulative and deceptive devices**
> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange —
>
> . . .
>
> (b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

Rule 10b-5 of the Securities and Exchange Commission, 17 C.F.R. § 240.10b-5, provides:

Sec. 240.10b-5 Employment of manipulative and deceptive devices.

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,

in connection with the purchase or sale of any security.

STATEMENT OF THE CASE

Overview

This petition presents two grounds for review and, ultimately, reversal by the Court. The first is a shockingly conspicuous error, wherein both of the courts below simply failed to so much as consider one of the claims asserted by the complaint; the Petitioners-Plaintiffs' claim for violation of the federal securities laws based upon the *affirmative misrepresentations* of the defendants. Despite undisputed (indeed, indisputable at the motion to dismiss stage) facts showing blatantly false public representations by Sofamor Danek Group, Inc. and the other defendants,[1] the materiality of which is readily apparent and has never been seriously questioned, the courts below erroneously and inexplicably failed to in any way address the Petitioners-Plaintiffs' affirmative misrepresentation claim. In addition, *had* the courts below evaluated the merits of or at all considered the affirmative misrepresentation claim, the clear and undisputed nature of the publicly issued untruths would necessarily have led to the conclusion but that, standing alone, the claim was patently sufficient to mandate that this case go forward.

Instead of addressing the merits of the claim pled based on SDG's affirmative misrepresentations, the courts below solely focused on an alternative claim based on the

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[1] Collectively, "SDG" or "the Company."

Company's failure to disclose to its investors and the investing public certain material information — the Petitioner-Plaintiffs' "omissions" claim. Although, unlike the Petitioners-Plaintiffs' affirmative misrepresentation claim, the courts below actually addressed the merits of the omissions claim, in so doing they completely misapplied the federal securities law applicable to such claims. Specifically, the courts confused the question of whether it was necessary to disclose the material information regarding certain of the Company's activities, with the question of whether the disclosure needed to express the information in pejorative terms or to explicitly predict the potential ramifications of those activities. The straightforward, undisputed facts, however, demonstrated that the Company was both surreptitiously and openly engaging in activities of a sort that would cause concern for any reasonable investor as to whether such conduct was legitimate and lawful, and whether that conduct subjected the Company and its shareholders to very real and potentially disastrous consequences, such as severe civil, administrative or even criminal sanctions. In addition, the undisputed facts established that the Company voluntarily chose to directly and publicly speak on the subject of the activities at issue, and in so doing falsely represented that it did not engage in such activities.

These two plain errors — the utter neglect to even address one well-pled claim (the affirmative

misrepresentation claim), and the facially obvious misapplication of relevant law with respect to another claim (the omissions claim) — are manifestly unjust to the defrauded investors of SDG and necessitate this petition.

Background

SDG, headquartered in Memphis, Tennessee, is a developer, manufacturer and marketer of spinal implant devices used in the surgical treatment of spinal degenerative diseases and deformities, and of products which increase stability during the healing of spinal trauma. At times relevant to this matter, all of SDG's products were marketed under "section 510(k)" approval from the FDA. Section 510(k) approval enables medical device manufacturers to avoid the expensive and lengthy human clinical trials and the more complex submissions required to prove safety and efficacy that are typical of requests for full pre-market approval.

Section 510(k) approval, however, is designed to be a calculated trade-off, with specific limitations. In particular, approval for eligible devices is limited to recognized, pre-existing uses of the devices. Recommending, labeling, marketing or otherwise promoting any medical device approved under section 510(k) for any use other than the authorized and recognized pre-existing use of the device is strictly forbidden, as it constitutes an unapproved "new use"

of the device. Recommending, labeling, marketing or otherwise promoting a section 510(k)-approved medical device for an unapproved "new use" is a violation of FDA regulations and, thereby, is unlawful. Violations of FDA regulations can subject the violators to various administrative and criminal sanctions, either of which may be quite severe. In addition, medical devices marketed and utilized in violation of FDA regulations often generate civil lawsuits, which routinely seek substantial monetary damages.

Under the so-called "medical judgment" rule, however, a physician can choose to use a medical device otherwise lawfully on the market for even those uses not specifically approved by the FDA, so long as the physician deems it to be in the patient's best interest. This apparent loophole provides a great incentive for unscrupulous companies to illicitly promote or encourage the use of their section 510(k)-approved devices for such unapproved uses, and can be extremely profitable for as long as the company can avoid either detection or enforcement action by the FDA.[2]

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[2] The reason this illicit practice can be tempting is obvious. If the company successfully encourages physicians to use its device under the "medical judgment rule" for non-approved uses, it not only has the potential for tremendously increasing demand for the device, but it enables the company to sell the device for these uses while avoiding the costs

In fact, it is exactly what occurred here.

Crucial to SDG's success was its Bone Plate and Screw Product Line ("BPSPL") which, as medical devices, were regulated by the FDA. During the relevant time, SDG had only obtained section 510(k) approval for its BPSPL and, therefore, the devices were approved only for certain recognized pre-existing uses. It is undisputed that, at the relevant time, use of the BPSPL for pedicular attachment[3] (a.k.a., "interpedicular segmental fixation") was **not** a recognized, pre-existing use of the devices and, therefore, use of the BPSPL for pedicular attachment was not a use approved by the FDA (in other words, a "new use"). The BPSPL could be used for pedicular attachment, however, if a physician (pursuant to the medical judgment rule) deemed such use to be in his patient's best interest. Nevertheless, the fact remained that marketing, labeling, promoting or in any way encouraging the use of its BPSPL as suitable for pedicular attachment was unauthorized and illegal, and if SDG engaged in such activities it could subject the Company to myriad civil, administrative, or even criminal sanctions.

Notwithstanding the prohibition on marketing,

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associated with the expensive clinical and human trials necessary for the pre-market approval process — expenses that competitors who play by the rules necessarily incur.

[3] The pedicle is a bony support structure of the spine.

labeling, promoting or otherwise encouraging the use of its BPSPL for pedicular attachment, it is uncontroverted that SDG both openly and surreptitiously engaged in such activities. For example, SDG secretly funded the so-called Spinal Science Advancement Foundation ("SSAF"), which in turn sponsored numerous programs promoting the use of SDG's BPSPL for pedicular attachment. SDG also directly funded numerous seminars and programs that not only promoted the use of its BPSPL for pedicular attachment, but actually *demonstrated* such use. Indeed, SDG went so far as to station its sales persons right inside operating rooms, who would physically assist in actual spinal surgeries where its BPSPL was used for pedicular attachment.

By all accounts, SDG's promotional activities geared to convincing physicians to use (through the medical judgment rule loophole) its BPSPL for the otherwise non-approved use of pedicular attachment was tremendously successful. Indeed, in various public filings[4] SDG credited a

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[4] The Court of Appeals correctly held that passages from certain public filings by the Company, made part of the record by the defendants on their motion to dismiss, could properly be considered in conjunction with and in support of the complaint, notwithstanding that the complaint did not expressly reference the passages. *See* Final Sixth Circuit Court Opinion, Appendix A, at 18-19, n.2.

great deal of its apparent success and future bright outlook to an increase in spinal surgeries in general, and an increase in spinal surgeries using its devices in particular. Apparently, however, SDG's BPSPL devices began to fail in numerous pedicular attachment applications, the exact same applications for which they were not FDA-approved in the first place, but for which applications the devices had gained a certain amount of acceptance as a result of SDG's various promotional activities. Consequently, and not unexpectedly, numerous civil product liability lawsuits were instituted against SDG as a result of the marketing and use of its BPSPL for pedicular attachment applications. As a further result, and likewise not unexpectedly, SDG's business operations and future outlook substantially suffered as a result, its stock price precipitously declined, and investors, having never received timely and candid disclosure from the Company regarding its undisputed promotional activities, were left holding the bag.

In response, certain defrauded SDG investors initiated class action lawsuits on their own behalf and on behalf of similarly situated defrauded SDG investors. By consolidated amended complaint, the Petitioners-Plaintiffs asserted claims based on SDG's violations of the federal securities laws, specifically, Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, [15 U.S.C. §§ 78j(b) and 78t(a)] and Rule 10b-5 of the Securities and Exchange Commission [17 C.F.R. § 240.10b-5]. On SDG's motion to dismiss, the

District Court *never even considered* Petitioners-Plaintiffs' Section 10(b) and Rule 10b-5 claim based on SDG's *affirmative misrepresentations*. Rather, the District Court merely evaluated the omissions claim, and even then misapplied applicable law. Stunningly, the Court of Appeals followed suit, also completely ignoring the Section 10(b) and Rule 10b-5 claim based on affirmative misrepresentation. In addition, in evaluating the omissions claim, the Court of Appeals likewise misapplied the relevant law, becoming pre-occupied with SDG's red-herring concerning whether the Company need disclose that its activities were "illegal," as opposed to the real question concerning the need to disclose the facts of the undisputed activities themselves.

REASONS FOR GRANTING THE WRIT

I. The decisions below are plainly erroneous and manifestly unjust, as the courts below simply *ignored* and *never considered* the clearly viable claim stated in the complaint for violation of the federal securities laws based on the defendants' untrue statements of material fact, which claim was based on clear and undisputed *affirmative misrepresentations* made by the defendants.

By its plain language, a claim asserted under SEC Rule 10b-5 may be grounded upon an affirmative misrepresentation. 17 C.F.R. § 240.10b-5(b) (unlawful under the federal securities laws to "make any untrue statement of a material fact . . ."). *See also SEC v. Texas Gulf Sulphur Co.*, 401 F.2d 833, 862 (2d Cir. 1968) (*en banc*), *cert. denied sub nom.*, *Coates v. SEC*, 394 U.S. 976 (1969) ("Rule 10b-5 is violated whenever assertions are made [that] are *false* or misleading..."). For reasons that defy explanation, however, neither court below undertook to consider the viability of the federal securities law claim asserted by Petitioners-Plaintiffs based on SDG's flagrant and unquestionable affirmative misrepresentations. This complete and utter failure to so much as evaluate the claim is an error so plain and egregious that this Court cannot permit it to stand. On this basis alone, this Court should grant this petition, issue the writ, and reverse and remand.

Furthermore, from the facts pled in and favorable inferences drawn from the consolidated amended complaint,[5] two things are abundantly clear.[6] First, that SDG publicly and affirmatively represented to its investors and the market in general that it was not engaged in conduct or activities geared to promoting its BPSPL for unapproved uses (*e.g.*, for pedicular attachment). Second, that given SDG's several and undeniable promotional activities (*e.g.*, secret funding of the SSAF, which in turn sponsored numerous seminars encouraging use of the BPSPL for pedicular attachment, funding seminars and programs demonstrating actual use of the BPSPL for pedicular attachment, and having SDG sales people assist in actual surgeries using the BPSPL for the unapproved use of pedicular attachment) these public and affirmative representations were *patently untrue*. Based on the foregoing, it is palpably evident that a Rule 10b-5 claim was adequately stated, and that this case should be permitted to proceed.

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[5] Including the facts in and favorable inferences drawn from passages of certain SDG public filings, which were made part of the record below. *See supra,* note 4.

[6] Since the matter was before the courts below on a motion to dismiss, all factual allegations were accepted as true and read in the light most favorable to the Petitioners-Plaintiffs.

II. When a company is engaged in activities which place it and its investors in clear jeopardy of serious and damaging negative consequences, such as severe and possibly crippling civil, administrative or even criminal sanctions, the federal securities laws mandate, under the basic tenet of complete and accurate disclosure, that the company disclose the activities; this is particularly true once the company has voluntarily chosen to speak on the subject, denying that it is engaged in any such activities. As such, the Court should grant this petition and issue the writ requested in order to reverse the opinion below which, through its misapplication of applicable law, is clearly erroneous and in stark contrast to the fundamental principles and purposes of the federal securities law.

Although the lower courts did address the Petitioner-Plaintiffs' omissions claim, they nevertheless clearly erred in their application of the relevant law. Specifically, the Court of Appeals plainly erred in its failure to find any duty on the part of SDG to disclose any of its numerous activities unmistakably geared to promoting the BPSPL for the unapproved use of pedicular attachment. SDG's duty to disclose, however, is clear on at least two bases.

First, even if SDG would otherwise have had no duty, SDG voluntarily chose to speak on the subject, and directly addressed the issue of its promotional activities (telling the

investing public that it did not engage in such activities). Once SDG took it upon itself to speak at all, SDG necessarily undertook the duty to insure not to "omit to state a material fact necessary in order to make the statements made . . . not misleading." *See* 17 C.F.R. § 240.10b-5(b). *See also First Virginia Bankshares v. Benson,* 559 F.2d 1307, 1317 (5th Cir. 1977), *cert. denied*, 435 U.S. 952 (1978) (even where a company would normally not have a duty to speak, once it undertakes to speak at all it undertakes the duty to speak truthfully).

Secondly, the Court of Appeals erroneously concluded that, in any event, SDG had no duty to disclose its undisputed activities geared to promoting its BPSPL for the unapproved use of pedicular attachment because it was only "soft" information. The court was clearly mistaken, as the specific, concrete promotional activities SDG engaged in are facts that are at least as "hard" as the merger negotiations activity at issue in *Basic, Inc. v. Levinson,* 485 U.S. 224 (1988); disclosing and describing the existence of either of the activities themselves demands neither prediction nor speculation. Although, whether SDG's activities in promoting the use of its BPSPL for the unapproved use of pedicular attachment constituted chargeable illegal conduct, and whether such illegal conduct might actually result in significant civil, administrative or even criminal sanctions, might be regarded as calling for speculation or prediction, the

fact that SDG was *engaged in the specific, concrete, promotional activities themselves* is altogether different. It was apparently this distinction that evaded the Court of Appeals, as its opinion evinces a concern for requiring SDG to describe its conduct in perjorative terms. While such a concern may be altogether legitimate, it nonetheless entirely misses the mark. Under the federal securities laws, SDG, both due to its voluntary decision to offer untruthful or misleading statements on the subject, as well as the plainly material nature of such information in its own right, was required to disclose to unwary investors the cold, *hard* facts of its promotional activities; after the required disclosure, SDG investors and the market could have speculated and postulated for themselves as to the obvious potential ramifications and the likelihood of their fruition. *See, e.g., In re Par Pharm., Inc. Sec. Litig.*, 733 F. Supp. 668, 677-78 (S.D.N.Y. 1990) (although the company was not required to disclose the predicted *consequences* of its bribery scheme, it was a jury question regarding whether it should have disclosed *the facts of the scheme itself*). Requiring such disclosure and having fully informed investors is the *raison d'etre* of our federal securities laws. *E.g., Santa Fe Indus. v. Green,* 430 U.S. 462, 477-78 (1977) (the Supreme Court "repeatedly has described the fundamental purpose 'of the [Exchange] Act as implementing a philosophy of full disclosure.'") (quoting *SEC v. Capital Gains Research*

Bureau, Inc., 375 U.S. 180, 186 (1963)).

CONCLUSION

The most obvious and most egregious error of the lower courts is their wholesale failure to address a claim whose legal basis is clearly granted by the plain language of Rule 10b-5. The failure to so much as address Petitioners-Plaintiffs' claim based on SDG's clear affirmative misrepresentations is, standing along, ample justification to grant this petition.

In addition, with respect to Petitioners-Plaintiffs' omissions claim, it is abundantly clear that the courts below fundamentally misapplied the federal securities laws, denying the defrauded investors of SDG the protections the federal securities laws are designed to afford them. Of additional import, the published opinion of the Court of Appeals is contrary to the basic tenets of the federal securities laws regarding the complete and accurate disclosure required of companies who tap into the great resource of capital available through our national securities markets. As such, the opinion stands in stark contrast to the expectations and understandings of those who provide the capital to our national securities markets, which, to a great extent, are psychologically driven; investors freely commit their capital relying on the presumption of the market's fundamental integrity, and on the

principles of full and complete disclosure as mandated by the federal securities laws. Moreover, investors rely on the remedies afforded by the federal securities laws when publicly owned and traded companies fail to comply with their statutory duties pertaining to disclosure. Permitting to let stand the patently erroneous misapplication of the federal securities laws evidenced by the underlying opinion risks other courts misguidedly following suit and, ultimately, upsetting this delicate balance. *See, e.g., Basic,* 485 U.S. at 235 ("'The importance of accurate and complete issuer disclosure to the integrity of the securities markets cannot be overemphasized. To the extent that investors cannot rely upon the accuracy and completeness of issuer statements, they will be less likely to invest, thereby reducing the liquidity of the securities markets to the detriment of investors and issuers alike'.") (quoting *In re Carnation Co.*, Exchange Act Release No. 22214, 33 SEC Docket 1025, 1030 (1985)).

For the reasons stated herein, therefore, the Court should grant this Petition for Writ of *Certiorari.*

Respectfully submitted,

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Dated: January 6, 1998

Table of Appendix Contents

Final Opinion,
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filed 11/6/95, Western Dist. of TN D1-D1

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Suggestion for Rehearing *En Banc*,
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Consolidated Amended Complaint,
filed 9/2/94, Western Dist. of TN F1-F62

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

OPINION

Sixth Circuit Case Nº. 95-6491/6592
Filed August 14, 1997

Pages A-1 thru A-28

RECOMMENDED FOR FULL-TEXT PUBLICATION
Pursuant to Sixth Circuit Rule 24

ELECTRONIC CITATION: 1997 FED App. 0244P (6th Cir.)
File Name: 97a0244p.06

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

In Re: SOFAMOR DANEK GROUP, INC.

FILED
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BRUCE G. MURPHY, RANDY OWEN, MARY KENNEDY, and LYNDA KRAMER,

Plaintiffs-Appellants,

MIKE ROBERTS,

Plaintiff,

v.

SOFAMOR DANEK GROUP, INC., E. RON PICKARD, LAURENCE Y. FAIREY, LEANDER D. BEARD, GEORGE F. RAPP, MILES D. IGO, ALAN J. OLSEN, YVES PAUL COTREL, and PHILLIPE COTREL,

Defendants-Appellees.

Nos. 95-6491/6592

Appeal from the United States District Court
for the Western District of Tennessee at Memphis.
No. 94-02303--Jerome Turner, District Judge.

Argued: October 22, 1996
Decided and Filed: August 14, 1997

Before: **MERRITT, BROWN,** and **NELSON,** Circuit Judges.

COUNSEL

ARGUED: Steven J. Toll, COHEN, MILSTEIN, HAUSFELD & TOLL, Washington, D.C., for Appellant. Kenneth M. Kramer, SHEARMAN & STERLING, New York, New York, for Appellee. **ON BRIEF:** Steven J. Toll, COHEN, MILSTEIN, HAUSFELD & TOLL, Washington, D.C., Alexander W. Wellford, Jr., HUMPHREYS, DUNLAP, WELLFORD, ACUFF & STANTON, Memphis, Tennessee, for Appellant. Kenneth M. Kramer, SHEARMAN & STERLING, New York, New York, Earle J. Schwarz, Saul C. Belz, Jennifer W. Sammons, WARING COX, Memphis, Tennessee, for Appellees.

OPINION

DAVID A. NELSON, Circuit Judge. This is an appeal from the dismissal of five consolidated securities fraud cases. The plaintiffs — each of whom in 1993 and/or 1994 made one or two purchases of between 100 and 500 shares of common stock in the defendant corporation — allege that they and members of a shareholder class they purport to represent paid inflated prices for their stock because the company and its officers and directors publicly

misrepresented the company's marketing practices and failed to disclose (1) that medical devices manufactured by the company were being promoted for a use not approved by the United States Food and Drug Administration and (2) that medical devices which the company lent to hospitals without initial charge under a "loaner kit" program were ultimately being sold to the hospitals at twice the regular list price.

Granting a motion for dismissal under Rule 12(b)(6), Fed. R. Civ. P., the district court concluded that the alleged misrepresentations and failures to disclose were not actionable under the federal securities laws and that the plaintiffs had failed to state a claim for common law fraud and negligent misrepresentation. We find ourselves in substantial agreement with the district court's analysis, and we shall affirm the dismissal.

I

Defendant Sofamor Danek Group, Inc., which has its headquarters in Memphis, Tennessee, was organized in 1983 as an Indiana corporation. Originally named Biotechnology, Inc., it was renamed Danek Group, Inc., a few years later. The company received its present name in June of 1993, when it acquired all of the capital stock of Sofamor, S.A., a privately held French company, in exchange for newly issued shares of Danek common stock.

The initial public offering of Danek stock took place in 1991, at which time 1.8 million shares — approximately 22 percent of all shares outstanding after the offering — were sold at $15.00 per share. The stock (which was subsequently split two-for-one) was traded on the over-the-counter market until shortly after the Sofamor acquisition; Sofamor Danek was then listed on the New York Stock Exchange. As of December 31, 1993, the company had 24,369,838 shares of common stock outstanding. During the fourth quarter of 1993 the price per share ranged between a low of $27.25 and a high of $38.75.

Sofamor, S.A., had been controlled by Dr. Yves Paul Cotrel (one of the defendants herein) and members of his family. A proxy statement/prospectus issued in connection with Danek's proposed acquisition of Sofamor indicated that upon completion of the acquisition the current officers and directors of Danek would be left with ownership of roughly one quarter of the outstanding stock of Sofamor Danek. Dr. Cotrel and his family — who were to receive two seats on the Sofamor Danek board of directors — would own a slightly smaller percentage.

It was further disclosed that the disposition of Sofamor stock would be a taxable transaction; that the Sofamor shareholders intended to sell a significant portion of the newly issued shares, amounting to roughly 10 percent of Sofamor Danek's total outstanding stock; that the Sofamor

shareholders had entered into an agreement designed to provide for an orderly resale; and that prevailing market prices for Sofamor Danek stock could nonetheless be adversely affected by substantial sales. The proxy statement/prospectus also noted that there had been significant volatility in the market for Danek stock since the initial public offering, which volatility might continue or increase from time to time in the future.

Both Danek and Sofamor, as the proxy statement explained, were primarily engaged in the business of developing, manufacturing and marketing spinal implant devices for surgical use. Danek entered this business segment in the mid-1980s, producing spinal implant devices at an Indiana manufacturing facility and distributing them through a subsidiary located in Memphis. By 1991, according to a prospectus issued when the company went public, Danek had two main product lines; one consisted of specialized systems of support rods and eyebolt locking mechanisms, and the other — the Danek Bone Plate and Screw Product Line — consisted of devices attached to bones in the spine to achieve fixation during healing. Other fixation and implant systems had been added by 1993.

The principal products of Sofamor, S.A., included the Cotrel-Dubousset spinal instrumentation system, which was manufactured and sold in France beginning in 1983, and a newer line designed for the treatment of degenerative

diseases of the lumbo-sacral spine. By 1993 Sofamor products were marketed in over 45 countries, including the United States.

Danek's 1991 prospectus contained a "Government Regulations" section noting that within the United States the Food and Drug Administration had authority over the company's medical devices by reason of the Safe Medical Devices Act of 1990 and the 1976 Medical Devices Amendment to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. The prospectus went on to say that all products currently marketed by Danek had gone through a regulatory procedure known as "Section 510(k) notification," a relatively simple method of obtaining FDA clearance for devices "substantially equivalent" to products legally marketed in the past. (The 1976 Act established grandfather rights for products that had been on the market before May 28, 1976.) Section 510(k) notification, according to the prospectus, is far less complicated than the "premarket approval" required for devices that are not eligible for 510(k) treatment. A premarket approval application was said to be "a much more complex submission that typically includes a long follow-up of both animal and human studies."

In 1990, as the prospectus disclosed, the FDA advised Danek and a number of other manufacturers that they were not to promote bone plates, sacral screws, etc. for

"pedicular attachment," which was said to be a "new use" for these devices. This meant that Danek could not label or promote its products as suitable for attachment to the pedicle — a boney support structure on the anterior aspect of the vertebral bodies that make up the human spine. Danek revised its promotional literature, the prospectus stated, to remove any reference to pedicular attachment. The prospectus noted that the company could not rule out the possibility of regulatory action, however, and said that such action might include an injunction against any distribution of the Danek Bone Plate and Screw Product Line. The possibility of such regulatory action was also disclosed in the annual Form 10-K filings made with the Securities and Exchange Commission for 1991 and each subsequent year through 1993.

In Europe and Asia, as the 1993 proxy statement explained, Sofamor was able to sell devices with screws intended to be inserted in the pedicle. Because use of a pedicle screw was not exempt from premarket approval by the FDA under § 510(k), however, Sofamor was said to have applied for permits to conduct clinical trials of pedicle screws preparatory to filing a premarket approval application for this use in the United States.

In connection with a discussion of "*Possible Regulatory Action Involving the Danek Bone Plate and Screw Product Line,*" the proxy statement also explained that as part of the

practice of medicine — which is not itself regulated by the FDA — American physicians were free to use Danek screws (or any other products) in the pedicle portion of the vertebra if, in the exercise of their medical judgment, the physicians deemed such use to be in their patients' best interest. "Although this practice [also referred to as "interpediculiar segmental fixation"] probably will continue in the future," the proxy statement said, "Danek cannot predict nor does it encourage the use of products for unapproved applications." Similar statements appeared in the company's 10-K forms for fiscal years 1992 and 1993.

The FDA might have disagreed with the proposition that Danek did not "encourage" use of the company's products for interpediculiar segmental fixation. In August of 1993, as the company disclosed in its Form 10-K for that year, "Danek and six other companies received warning letters from the FDA, primarily regarding the issue of supporting medical education programs that actually 'demonstrate' the use of screws in the pedicle of the spine."

The other marketing practice relevant in this litigation involves Danek's so called "loaner set" program. The 1991 prospectus said this on the subject:

> "In meeting the needs of hospitals, the Company offers various instrument and implant purchase alternatives, as well as overnight shipment of implant systems for next day surgery. One of the Company's purchase

alternatives consists of the Company furnishing a full set of products to a hospital without initial charge. After components are used during surgery, the set is returned to the company and the hospital is then charged only for the components used at a premium price per piece."

The company's Form 10-K for 1993 showed a year-end loaner set inventory of $6,065,000 — representing more than a ten-fold increase over the corresponding number in the Form 10-K for 1991. The company's regular inventory increased over the same time period from $4,892,000 to $21,189,000. Net sales from all sources came to $161,794,000 in 1993, according to the company's Form 10-K for that year, as opposed to 1991 sales which the same report set at $74,548,000.

II

The present litigation began in April of 1994, when plaintiff Bruce G. Murphy — who alleged that he had purchased 100 shares of Sofamor Danek stock on August 20, 1993, at $33 ¼ per share — filed a class action complaint against the company and certain of its officers and directors in the United States District Court for the Western District of Tennessee. Four similar complaints were subsequently filed in the same court by other plaintiffs, and the cases were consolidated pursuant to a

consent order that called for the complaints to be replaced by a single consolidated complaint. Such a complaint was then duly filed on behalf of the five named plaintiffs.

The consolidated complaint alleges that the named plaintiffs bought a total of 1,770 shares of Sofamor Danek stock at various times between February of 1993 and April of 1994 at prices ranging from $20⅜ per share to $36 per share. The complaint further alleges that between November of 1993 and February of 1994 the individual defendants — several of whom were officers of the corporation and all of whom served on its board of directors — sold a total of 728,043 shares (a little under three percent of all shares outstanding) at prices ranging from a low of $29.94 per share to a high of $36 per share. Named as the single biggest seller, not surprisingly, was Dr. Cotrel; he was said to have disposed of 255,354 shares at gross prices totaling $7,761,646.

In December of 1993, according to the complaint, the television program "20/20" ran a segment on the dangers of using pedicle screws in spinal fusion operations. Four days later the FDA issued an "Update on Pedicle Screws" in which it said that although such screws had been used on approximately 300,000 people in the United States alone, "not enough is known about the possible short-term adverse effects of the screws . . . nor about their long-term effectiveness." Making reference to the letter of the

previous August in which the FDA had warned manufacturers not to promote the use of orthopedic screws in the pedicles of the spine, the update reiterated that it was illegal for manufacturers to promote pedicular use through professional advertising and training courses.

In mid-January of 1994, the complaint says, Sofamor Danek announced that it had been sued by five patients who alleged that surgical screws had been used in their spines "illegally." The complaint implies that the lawsuit was inspired by the "20/20" television program.

The complaint sets forth a wealth of sales and earnings data reported by the company, with accompanying commentary, including the results for the first quarter of 1994. In a press release issued on April 21, 1994, we are told, the company reported that first quarter sales had increased 13 percent over the figure for the corresponding period in 1993. This growth in sales was below the expectations of most stock analysts, the complaint says.

The company allegedly reported further bad news in a conference call with analysts on the same day as the press release. The company advised that it had recently been notified that its largest United States distributor would not meet its purchase commitment for the second quarter of 1994. "During the conference call," the complaint continues, "the Company also admitted that surgeons' fears

of litigation relating to the off-label use of spinal screws in the pedicle was most likely negatively impacting spinal implant sales."

Primarily as a result of the April 21 statements, according to the complaint, the price of the stock dropped 3 ¾ points that day. It fell another 3⅛ points on April 22, 1994, closing at $12¾ per share. (It is a matter of public record that the price subsequently recovered; not until 1997, however, did it exceed $40 per share.)

The complaint avers that during the period from February 8, 1993, through April 21, 1994, the defendants made deceptive and materially false and misleading statements which, coupled with the defendants' failure to disclose information that allegedly ought to have been disclosed, caused the company's stock to trade at artificially inflated prices. The allegations in this regard are divided into three categories.

First, according to the complaint, the market was unaware that the company was improperly promoting its products for pedicular use and that such promotion was having a material impact on the company's financial position. The complaint says that it was not uncommon for the company's sales representatives to assist surgeons during operations in which Danek screws were inserted in the pedicle; that the company surreptitiously sponsored seminars at which

pedicle fixation was promoted; that the company helped create and fund a non-profit foundation (the Spinal Science Advancement Foundation) to sponsor programs where physicians could see demonstrations of plate and screw pedicle fixation; and that in a conference call with stock analysts during October of 1993, the company's president "downplayed" the FDA letter in which the company had been warned that its support of such programs constituted promotion of medical devices for an unapproved use in violation of the law.

Second, according to the complaint, the market was ignorant of the fact that "improper" sales through the loaner set program constituted a significant source of the company's earnings. In this connection the complaint alleges that most hospitals believed they would pay only a small premium for items used from the loaner sets; that in fact hospitals were often charged premiums 100 percent over the regular list price; that the company immediately eliminated such premiums when hospitals complained, although sales representatives were sometimes banned from hospitals upon discovery of the premiums; that the company's president and executive vice-president "downplayed any positive financial effects from loaner sales" in the conference call with stock analysts in October of 1993; and that on January 1, 1994, the company reduced its loaner set premiums to approximately 29 percent.

Third, according to the complaint, the defendants failed to disclose in a timely manner that the exclusive distributor for product lines that accounted for 34 percent of Sofamor Danek's sales was not going to meet its purchase commitment for the second quarter of 1994 and would probably have its distribution contract terminated. The dismissal of this claim has not been pursued on appeal. We shall not discuss the claim further, therefore, except to note that problems associated with the termination of the distributor's contract contributed, as the plaintiffs themselves have alleged, to the decline in the price of Sofamor Danek's stock.

On October 5, 1995, after full briefing, the district court entered a 30-page order granting the defendants' motion to dismiss the consolidated complaint with prejudice.[1] The judgment implementing this decision was entered on November 6, 1995. Timely notices of appeal have been filed with respect to both the order and the judgment.

III

The propriety of a dismissal pursuant to Rule 12(b)(6), Fed. R. Civ. P., is a question of law that is subject to *de*

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[1]The case was decided shortly before enactment of the Private Securities Litigation Reform Act of 1995, which is codified at 15 U.S.C. § 78u-78u-5. The Reform Act has no direct application here.

novo review. All factual allegations made by the plaintiff are deemed admitted, see *Sinay v. Lamson & Sessions Co.*, 948 F.2d 1037, 1039 (6th Cir. 1991), and ambiguous allegations must be construed in the plaintiff's favor. *Id.* at 1039-40. The district court may not grant a Rule 12(b)(6) motion based on disbelief of factual allegations in the complaint. See *Columbia Natural Resources, Inc. v. Tatum*, 58 F.3d 1101, 1109 (6th Cir. 1995), *cert. denied*, 116 S. Ct. 1041 (1996). Nevertheless, our standard of review "require[s] more than the bare assertion of legal conclusions." *Id.* "[W]e need not accept as true legal conclusions or unwarranted factual inferences." *Morgan v. Church's Fried Chicken*, 829 F.2d 10, 12 (6th Cir. 1987).

Section 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5, have the effect of prohibiting the commission of fraud in connection with the sale or purchase of securities. *Gross v. Summa Four, Inc.*, 93 F.3d 987, 992 (1st Cir. 1996). To state a cause of action under § 10(b) and Rule 10b-5 a plaintiff must plead that the defendant made a false statement or omitted to state a material fact which should have been disclosed, and that the plaintiff's reasonable reliance on the statement or omission proximately caused the plaintiff's injury. See *Aschinger v. Columbus Showcase Co.*, 934 F.2d 1402, 1409 (6th Cir. 1991); *San Leandro Emergency Medical Group Profit Sharing Plan v. Philip Morris Cos.*, 75 F.3d

801, 808 (2d Cir. 1996). Misrepresented or omitted facts are material only if a reasonable investor would have viewed the misrepresentation or omission as "having significantly altered the total mix of information made available." *Basic, Inc. v. Levinson*, 485 U.S. 224, 232 (1988) (internal quotation marks and citation omitted).

Before liability for non-disclosure can attach, the defendant must have violated an affirmative duty of disclosure. See *Basic*, 485 U.S. at 239 n. 17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5"). Ordinarily, at least, a company is under no duty to disclose the details of its merchandising practices. If we were prepared to assume in the case at bar that Sofamor Danek's merchandising practices constituted material information for purposes of the federal securities laws, however, that in itself would not be dispositive of the question whether disclosure was required. Materiality alone is not sufficient to place a company under a duty of disclosure. See *Philip Morris,* 75 F.3d at 808. See also *Roeder v. Alpha Indus., Inc.*, 814 F.2d 22, 26 (1st Cir. 1987).

The plaintiffs point to three circumstances that gave rise, in their submission, to a duty to disclose the allegedly illegal promotion of Sofamor Danek's products and the allegedly excessive prices charged for items selected from loaner kits. First, the plaintiffs argue that the defendants

advised the public of record revenues and earnings in statements that were incomplete and misleading because they attributed the company's success to such things as increased sales volume without properly explaining how the sales were being achieved. Second, the plaintiffs argue that Item 303 (a)(3)(ii) of SEC Regulation S-K, 17 C.F.R. § 229.303(a)(3)(ii), obligated the defendants to disclose the company's allegedly problematical marketing practices in the portion of the company's periodic SEC filings devoted to "[m]anagement's discussion and analysis of financial condition and results of operations." Third, the plaintiffs argue that disclosure was required by reason of the substantial sales of Sofamor Danek stock made by a number of the company's officers and directors between November of 1993 and February of 1994. We shall discuss these arguments in turn.

A

During the "Class Period" — defined in the complaint as the period from February 8, 1993, through April 21, 1994 — the company reported a series of substantial increases in sales, coupled with increases in earnings for most, but not all, of the quarterly periods involved. In explaining the reasons for these increases, as the complaint notes, the company pointed to growth in the number of spinal implant operations being performed, increased demand for the company's products for use in these

operations, favorable shifts in the sales mix, "leveraging" of fixed manufacturing costs and general administrative expenses, improved manufacturing efficiencies, an increase in prices for selected spinal systems, the introduction of new products, and expanded international sales. "These statements and reports created the impression that SDG's [Sofamor Danek Group's] tremendous growth in revenues and earnings was due to an increase in legitimate unit sales of SDG's products," the complaint avers. "Defendants were aware this was not the case," the complaint continues, and "were aware during the Class Period that much of SDG's sales success had been due to SDG's illicit promotion of its products for use in the pedicle area of the spine." Moreover, the complaint alleges, "defendants disavowed any knowledge of wrongful promotion of pedicle screws,"[2] and they "downplayed any positive

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[2]The only example of such disavowal cited in the complaint was the conference call with stock analysts on October 20, 1993, when the company's president allegedly downplayed the FDA's August warning letter and "stated that SDG would continue to comply with the FDA rules regarding medical education." On appeal, the plaintiffs also cite passages in the 10-K forms for 1992 and 1993 where the company said that it could not predict the use of products for applications not approved by the FDA and did not encourage such use. The defendants maintain that the plaintiffs may not rely on 10-K material to which there was no express reference in the complaint. These public filings were made part of the record by the defendants, however, and the passages in question are consistent with the complaint's allegation that the defendants disavowed any knowledge of wrongful promotion. We agree with the plaintiffs that the Form

financial effects from loaner sales."

The sales and earnings data publicly reported by Sofamor Danek during the Class Period are "hard" numbers, the accuracy of which has never been challenged by the plaintiffs.[3] Neither have the plaintiffs pointed to any affirmative misstatement in the company's explanations of the numbers. Thus we must take it as true that more spinal implant procedures were being performed, that demand for the company's products was increasing, that favorable shifts in the sales mix were occurring, that fixed costs were being spread over an increased number of units, that manufacturing efficiencies were being achieved, that the company had raised certain prices, that new product lines were being sold, and that international sales were expanding.

The proposition that the company was engaging in illegal promotion of its products when it helped fund the Spinal

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10-K material may be taken into consideration here.

[3]It is clear that a violation of federal securities law cannot be premised upon a company's disclosure of accurate historical data. See *In re Convergent Tech. Sec. Litig.*, 948 F.2d 507, 512-13 (9th Cir. 1991). The disclosure of accurate historical data does not become misleading even if less favorable results might be predictable by the company in the future. See *In re Verifone Sec. Litig.*, 784 F. Supp. 1471, 1484-85 (N.D. Cal. 1992), *aff'd*, 11 F.3d 865 (9th Cir. 1993).

Science Advancement Foundation and allowed its sales representatives ("independent commission sales representatives," according to the 10-K forms) to attend operations where surgeons made attachments to the pedicle is not a proposition that can fairly be said to fall in the category of "hard" information. Hard information "is typically historical information or other factual information that is objectively verifiable . . . ." *Garcia v. Cordova*, 930 F.2d 826, 830 (10th Cir. 1991). Such information is to be contrasted with "soft" information, which includes predictions and matters of opinion. See *Lewis v. Chrysler Corp.*, 949 F.2d 644, 652 (3d Cir. 1991). The legality of Sofamor Danek's support for the non-profit foundation, for example, was a matter of opinion — "soft information." And "our cases firmly establish the rule that soft information . . . must be disclosed only if . . . virtually as certain as hard facts." *Starkman v. Marathon Oil Co.*, 772 F.2d 231, 241 (6th Cir. 1985), *cert. denied*, 475 U.S. 1015 (1986).

As we have seen, Sofamor Danek did disclose its receipt of the warning letter from the FDA regarding the company's support for medical programs demonstrating the use of screws in the pedicle. In discussions with stock analysts, it is true, the company "downplayed" the significance of the warning letter — but any analyst could easily obtain a copy of the letter and could make an

independent judgment of its significance. Each of the company's 10-K forms explicitly mentioned the risk that the FDA might obtain an injunction against any distribution of the Bone Plate and Screw Product Line — and if regulatory action had actually been initiated against the company, we have no reason to suppose that it would not have been reported.

The hard fact is that no regulatory action was initiated during the Class Period. And as far as we have been advised, none has been initiated to date. If the company had publicly opined that its support of the nonprofit foundation was illegal, and if it had publicly predicted that the FDA would move against the company, the opinion would have come to look increasingly questionable with the passage of time, and the prediction would have proved to be flatly erroneous. This illustrates, we think, why predictions not "substantially certain to hold," like most matters of opinion, simply do not come within the duty of disclosure. See *Starkman*, 772 F.2d at 241.

By the same token, we see nothing in the company's public statements which gave rise to a duty to disclose more than was disclosed about the loaner kit program. At the very outset of its life as a publicly traded corporation, Danek stated publicly that hospitals were charged premium prices for loaner kit components not returned to the company. It was Danek that bore the cost of carrying

loaner kits in inventory and Danek that bore the risk of obsolescence — so the charging of a premium for loaner kit components that the hospitals ultimately decided to use was hardly surprising. Whether the premium was so high that the company should have been able to predict that it would prove counterproductive was clearly a matter of opinion — soft information as to which there was no duty of disclosure.

B

Item 303(a)(3)(ii) of SEC Regulation S-K, 17 C.F.R. § 229.303(a)(3)(ii) — an item that pertains to "[m]anagement's discussion and analysis of financial condition and results of operations" for full fiscal years — obligates reporting companies to:

> "[d]escribe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed."

Instruction seven for this item draws a distinction between "forward-looking information," which need not be disclosed, and "presently known data which *will* impact upon future operating results, such as *known* future increases in costs of labor or materials." (Emphasis supplied.) Sofamor Danek could have had no way of knowing with the degree of assurance implied by the instruction that the merchandising practices in question would have a material adverse impact upon future operating results, and we do not read the plaintiffs' complaint as alleging facts sufficient to show a violation of Item 303. Indeed, Item 303 is not even cited in the complaint.

The defendants invite our attention, moreover, to several cases in which federal district courts have held that there is no private right of action under Item 303. See *In re Cypress Semiconductor Sec. Litig.*, [1992 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 97,060 N.D. Cal. Sept. 23, 1992); *In re Verifone Sec. Litig.*, 784 F. Supp. 1471 (N.D. Cal. 1992), *aff'd*, 11 F.3d 865 (9th Cir. 1993); *Alfus v. Pyramid Tech. Corp.*, 764 F. Supp. 598, 608 (N.D. Cal. 1991). The plaintiffs, in response, acknowledge that the courts have been reluctant to recognize a private right of action under Item 303. The plaintiffs suggest, however, that the absence of a separate cause of action "does not preclude plaintiffs from arguing . . . that defendants' disclosure duty under the Rule 10b-5 claim may stem from

Item 303." Perhaps so — but for reasons similar to those explained above, we do not find the argument persuasive.

C

Finally, the plaintiffs contend that the individual defendants' "massive insider trading" created a duty to disclose that pedicular use of Sofamor Danek products was being promoted illegally, through the non-profit foundation and otherwise, and that the company was charging unsustainable premiums for items sold from its loaner kits. Again we are not persuaded.

The plaintiffs have not asserted an explicit insider trading claim, as they acknowledge in their opening brief on appeal. Noting that "plaintiffs have not brought an insider trading claim against the defendants," District Judge Turner "decline[d] to accept plaintiffs' argument that the allegations of insider trading create a duty that is transferrable to the securities fraud claim against the corporate defendant or the individual defendants." In this connection the court cited *In re Seagate Tech. II Sec. Litig.*, 843 F. Supp. 1341, 1369 (N.D. Cal. 1994) (recognizing that "importing this duty to disclose" would result in potentially "enormous liability on insider traders — liability that could not anticipated by Congress").

Seagate seems correct to us. As explained in an article

entitled "Insider Stock Sales in Rule 10B-5 Corporate Disclosure Cases,"

> "*Seagate* provides a persuasive analysis. In addition to the enormous potential liability that selling insiders could face, the plaintiffs' theory in *Seagate* would eviscerate limitations on a corporation's duty to disclose information because there nearly always are some insiders selling stock in a given time period. Thus, corporations would be under a duty to disclose all information even colorably material, or face potential second-guessing in a subsequent disclosure suit. Such a rule would deluge investors with marginally useful information, and would damage corporations' legitimate needs to keep some information non-public." Jordan Eth & Michael Dicke, 1 Stan. J.L. Bus. & Fin. 97, 109 (1994) (footnote omitted).

IV

In addition to asserting federal securities fraud claims, the plaintiffs' complaint sets forth claims for fraud and negligent misrepresentation under the law of Tennessee. The district court recognized, and the parties do not dispute, that reliance is an element of these common law claims. *Cf. Edwards v. Travelers Insur. of Hartford, Conn.*, 563 F.2d 105, 113 (6th Cir. 1977). The district

court also recognized, and the parties likewise do not dispute on appeal, that the plaintiffs' complaint does not assert direct reliance by the plaintiffs on the alleged misrepresentations; rather, the complaint rests on a fraud-on-the-market theory.

Neither the courts of Tennessee nor federal courts applying Tennessee law have held that the fraud-on-the-market theory is enough to satisfy the reliance requirement for common law purposes. On the other hand, the theory has not been expressly rejected by the Supreme Court of Tennessee. In the absence of a state supreme court decision on the issue, we must do our best to predict whether the Supreme Court would require actual reliance before allowing recovery for common law fraud and negligent misrepresentation in Tennessee. See *Bailey Farms, Inc. v. Nor-Am Chemical Co.*, 27 F.3d 188, 191 (6th Cir. 1994) ("[t]o the extent that the state supreme court had not yet addressed the issue presented, it is our duty to anticipate how that court would rule") (citing *Mahne v. Ford Motor Co.*, 900 F.2d 83, 87 (6th Cir.), *cert. denied*, 498 U.S. 941 (1990)).

We believe the Tennessee Supreme Court, if faced with the facts of the plaintiffs' case, would require a showing of actual reliance as a condition of recovery for common law fraud or negligent misrepresentation. Tennessee's intermediate appellate courts have uniformly held that

fraudulent misrepresentation must be established by proof that the defendant actually relied on the plaintiff's representations. See *Edwards v. Bruce*, 1996 WL 383294, at *8 (Tenn. Ct. App. July 10, 1996) (an element of fraudulent misrepresentation is that "the plaintiff actually relied on the misrepresentation of the material fact"); *Edmundson v. Coates*, 1992 WL 108717, at *15 n. 1 (Tenn. Ct. App. May 22, 1992) (one element of fraudulent misrepresentation is "reasonable reliance," which means actual reliance). We have no reason to suppose that the Tennessee Supreme Court would hold otherwise in a context of the sort presented here.

With respect to negligent misrepresentation, Tennessee follows the Restatement (Second) of Torts, § 552 (1977). See *Ritter v. Custom Chemicides, Inc.*, 912 S.W.2d 128, 129 (1995). The majority of federal courts considering the question have held that § 522 of the Restatement requires actual reliance before a party may be held liable for negligent misrepresentation. See *Smolen v. Deloite, Haskins & Sells*, 921 F.2d 959, 964 (9th Cir. 1993) (under § 552 "negligent misrepresentation requires actual and justifiable reliance"); *In re Westinghouse Sec. Litig.*, 832 F. Supp. 948, 989 (W.D. Penn. 1993) (the "fraud on the market theory has never been made applicable to a common law claim of negligent misrepresentation . . ."); *Goldman Services Mechanical Contracting, Inc. v. Citizens Bank and*

Trust Co. of Paducah, 812 F. Supp. 738, 742 (W.D. Ken. 1992) (the "Restatement and its comments make clear that actual reliance on the information by the person for whom it was intended is required for liability for a negligent misrepresentation"). We think the Tennessee Supreme Court would follow the majority rule.

Setting aside the issue of actual reliance, the plaintiffs in the case at bar argue that they are entitled to a "presumption of reliance." In this connection the plaintiffs cite *Memphis Housing Auth. v. Paine, Webber, Jackson & Curtis, Inc.*, 639 F. Supp. 108, 113 (W.D. Tenn. 1986).

In *Memphis Housing*, a decision not to enter summary judgment for a defendant charged with securities fraud was based in part on the ground that the "'obligation to disclose and [the] withholding of a material fact establish the requisite element of causation in fact.'" *Id.* (quoting *Affiliated Ute Citizens v. United States*, 406 U.S. 128, 154 (1972)). But in *Memphis Housing* a duty to disclose had arisen under the federal securities laws. No corresponding duty exists under federal law in the case at bar. *Memphis Housing* is thus inapplicable here.

For the reasons stated above, and for substantially all of the reasons given by Judge Turner, the judgment entered by the district court is **AFFIRMED.**

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

ORDER DENYING PETITION FOR REHEARING AND SUGGESTION FOR REHEARING *EN BANC*

Sixth Circuit Case Nº. 95-6491/6592
Filed October 9, 1997

Pages B-1 thru B-2

Nos. 95-6491/6592

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
97 OCT 9

In Re: SOFAMOR DANEK GROUP, INC.	)
	)
	)
BRUCE G. MURPHY, RANDY OWEN,	)
MARY KENNEDY, and LYNDA KRAMER,	)
Plaintiffs-Appellants,	)
	)
v.	) **ORDER**
	)
SOFAMOR DANEK GROUP, INC.; ET AL.,	)
Defendants-Appellees.	)

Filed Oct. 9, 1997
LEONARD GREEN, CLERK

BEFORE: Merritt, Brown and **Nelson**, Circuit Judges.

The court having received a petition for rehearing en banc, and the petition having been circulated not only to the original panel members but also to all other active judges of this court, and no judge of this court having requested a vote on the suggestion for rehearing en banc, the petition for rehearing has been referred to the original panel.

The panel has further reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision of the case. Accordingly, the petition is denied.

ENTERED BY ORDER OF THE COURT

/s/ Leonard Green, Clerk

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

ORDER ON DEFENDANTS'
MOTION TO DISMISS

Civil Case Nº.: 94-2303-TUA
Filed October 3, 1995 at 3:28 p.m.

Pages C-1 thru C-35

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

FILED
95 OCT. 3

In Re SOFAMOR DANKE GROUP, INC.	)	
	)	
	)	No 94-2303-TUA
THIS DOCUMENT RELATES TO:	)	
ALL ACTIONS	)	

ORDER ON DEFENDANTS' MOTION TO DISMISS

This is a class action brought by stockholders of Sofamor Danek Group, Inc. ("SDG") alleging that between February 8, 1993 and April 21, 1994 (the "Class Period"), defendants Sofamor Danek Group, Inc., E. Ron Pickard, Laurence Y. Fairey, Leander D. Beard, George F. Rapp, Miles D. Igo, Alan J. Olsen, Yves Paul Cotrel (Y. Cotrel) and Phillipe Cotrel (P. Cotrel) made false and misleading statements and omitted material facts concerning the financial health of SDG which plaintiffs relied upon to their detriment. Specifically, plaintiff f s contend that defendants failed to disclose that SDG's tremendous growth in revenue and earnings was caused by SDG's "illicit promotion of its products and improper price gouging," instead of a legitimate increase in SDG's unit sales. Additionally, plaintiffs argue that defendants knew that one of SDG's principal

distributors was having significant difficulty selling SDG products and would not meet its purchase commitment for the second quarter of the 1994 fiscal year. Plaintiffs allege that when thin information was finally disclosed to the marketplace in late April and June of 1994, SDG stock plummeted causing plaintiffs' injury. Plaintiffs also allege that SDG had long planned to terminate this distributor but failed to disclose this information.

Presently before the court is defendants' motion to dismiss Plaintiffs' Consolidated Amended Class Action Complaint ("Complaint") pursuant -to Federal Rules of Civil Procedure 9 (b) and 12(b)(6). Defendants' motion rests on the following grounds:

1. The Complaint fails to allege any legally cognizable untrue statement or omitted fact and thus is not plead with particularity pursuant to Rule 9(b) and fails to state a claim under Rule 12(b)(6);

2. The Complaint fails to allege facts giving rise to a strong inference of scienter as required by Rule 9(b);

3. Plaintiffs fail to state a claim under Rule 12(b)(6) for control person liability against the individual defendants;

4. Plaintiffs' state law claims for common law fraud and negligent misrepresentation should be dismissed under Rule 12(b)(6) for failure to

adequately allege that plaintiffs actually relied on defendants' purported false statements.

1. RELEVANT FACTS

Defendant SDG develops, manufactures and markets spinal implant devices used in surgical treatment of spinal degenerative diseases and deformities and manufactures products which increase the stability during the healing of spinal trauma. SDG was created in June 1993 through the merger of Danek Group, Inc. with Sofamor, S.N.C. (a French company), both of which were former developers and manufacturers of spinal implants. All of SDG's products are marketed under Section 501(k) approval from the FDA. Section 501(k) purportedly enables manufacturers to avoid complex submissions required to prove safety and efficacy such as expensive and lengthy human clinical trials. SDG is a publicly traded company incorporated in Indiana with its headquarters in Memphis, Tennessee.

Plaintiffs contend that beginning on February 8, 1993, defendants began issuing various statements regarding the financial health of SDG that omitted other relevant material facts resulting in the public receiving misleading information about the company.

In these announcements, plaintiffs allege that defendants reported record sales and net income for Danek Group/SDG and erroneously attributed such growth to an increase in sales volume. Plaintiffs' pleading claims that on

April 21, 1994, after SDG had been issuing very positive company reports for over a year, SDG reported that although its net income rose for the quarter that ended on March 31, 1994, as compared to that same quarter the previous year, SDG's domestic sales had declined. The Complaint alleges that SDG blamed such slower sales on "caution" relating to the regulatory and legal environment surrounding certain aspects of spinal surgery and weather-related postponements of spinal surgery instead of reporting the "true" reason for the decline.

Also on April 21, 1994, SDG announced that it had been notified by Stuart-Medical/National Medical Specialty, Inc. ("NMS"), its largest U.S. distributor, that NMS would not meet its second quarter 1994 purchase commitment. Plaintiffs contend that the defendants' "surprise disclosures" caused SDG common stock to plunge 3-3/4 points on April 21, 1994 and drop another 3-1/8 points the next day. In its Form 10-Q for the period ending March 31, 1994, SDG stated that it expected sales trends would continue to be below growth rates front prior years on account of the notification from NMS and the "continuing regulatory and legal environment surrounding certain aspects of spinal surgery."

On June 23, 1994, SDG further announced that Sofamor S.N.C., its wholly owned subsidiary, had agreed as of June 30, 1994 to terminate its distribution agreement with NMS and pay NMS $25.5 million for the termination.

That payment included $13.75 million for the acquisition by SDC; of inventory and related assets, and $1 million for an agreement not to compete. SDG explained that $10 million of the $25.5 million paid to NMS would be recorded as a material one-time charge to earnings during the second and third quarters of 1994.

Relying on the factual contentions already set forth, the Complaint alleges that defendants violated s 10(b) and 20(a) of the Securities Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 of the Securities and Exchange Commission, by negligently misrepresenting or failing to disclose certain material facts regarding the financial status of SDG. Plaintiffs also claim that defendants committed common law fraud and negligent misrepresentation in violation of Tennessee law. Plaintiffs' Complaint raises three specific claims against SDG:

1. Defendants failed to disclose that SDG was improperly promoting its products for pedicular use and that such promotion had a material effect on the company's financial position;

2. Defendants did not properly disclose that a significant amount of SDG earnings were from improper "loaner" sales; and

3. Defendants failed to timely disclose that NMS would not meet its purchase commitment to SDG and that SDG was terminating its existing contract with NMS.

Therefore, the essence of the Complaint is that defendants induced them to purchase stock in SDG in reliance on defendants' fraudulent misrepresentations exaggerating the financial health of SDG. In addition, plaintiffs also allege, in support of an inference of scienter as an element of their claims, that the individual defendants illegally profited from their fraudulent activity through personal buying and selling of SDG securities in reliance on the non-public "insider" information they possessed.

II. DISCUSSION

A. Motion to Dismiss under Rule 9 (b)

Defendants move to dismiss plaintiffs' fraudulent conveyance claim on the grounds that plaintiffs have failed to plead that claim with particularity as required by Federal Rule of Civil Procedure 9(b). In addition, defendants argue that plaintiffs have not sufficiently raised a strong inference of scienter in their Complaint as required by the federal securities laws.

1. Failure to Plead with Particularity

Rule 9(b) provides in relevant part:

> Fraud, Mistake, Condition of the Mind. In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally.

Rule 9(b) must be viewed in conjunction with the somewhat countervailing principle articulated in Federal Rule of Civil Procedure 8(a) that calls for a liberal approach to the pleading requirements. See Michaels Building Co. v. Ameritrust Co., N.A., 848 F.2d 674, 679 (6th Cir. 1988) ("In ruling upon a motion to dismiss under Rule 9(b) for failure to plead fraud 'with particularity,' a court must factor in the policy of simplicity in pleading which the drafters of the Federal Rules codified in Rule 8."); Credit & Finance Corp. Ltd. v. Warner & Swasey Co., 638 F.2d 563, 566 (2d Cir. 1981); 5 Wright & Miller, Federal Practice Procedure: Civil § 1291, at 407 (1969).

Rule 8(a) sets forth its generally liberal view of the federal pleading requirements by stating:

> Rule-8. General Rules of Pleading
>
> (a) Claims for Relief. A pleading which sets forth a claim for relief . . . shall contain . . . (2) a short and plain statement of the claim showing that the pleader is entitled to relief . . . .

(emphasis added). In Michaels, the Sixth Circuit synthesized the admonitions of both Rules 8(a) and 9(b) and set forth a compromise test for determining whether a fraudulent concealment complaint is sufficiently well-pleaded. The factors that the Michaels court relied on to determine whether the fraud claim in that case was plead with particularity included:

> [specification of] the parties and the participants to the alleged fraud, the representations made, the nature in which the statements are alleged to be misleading or false, the time, place and content of the representations, the fraudulent scheme, the fraudulent intent of the defendants, reliance on the fraud, and the injury resulting from the fraud.

Michaels, 848 F.2d at (379 (footnote omitted); Coffey v. Foamex L.P., 2 F.3d 157, 161-62 (6th Cir. 1993); see also Bender v. Southland Corp., 749 F.2d 1205, 1216 (6th Cir. 1984) (to satisfy requirements of 9(b) complaint should allege the time, place and substance of the false representations, as well as the identity of the person making the misrepresentation) ; Memphis Housing Authority v. Paine, Webber, Jackson & Curtis, Inc., 639 F. Supp. 108, 110 (W.D. Tenn. 1986) ("Allegations that state the time, place, and substance of allegedly fraudulent statements, along with the identity of the person making them, satisfy Rule 9(b)."). In light of these suggested factors, it is also important to note that the driving force behind Rule 9(b) is "to provide a defendant fair notice of the substance of a plaintiff's claim in order that the defendant may prepare a responsive pleading." Michaels, 848 F.2d at 679; Coffey, 2 F.3d at 162.

Plaintiffs' Amended Class Action Complaint addresses all of the factors enunciated in Michaels and provides the defendants with sufficient information to craft

an effective response. The Complaint sets forth the general time-frame of when the alleged fraudulent statements were issued, as well as the identities of the parties involved. Pls.' Am. Compl. ¶¶ 23, 37-65. Plaintiffs also adequately describe the content of the alleged fraud. Id. at ¶¶ 71-111. The alleged fraudulent scheme and defendants, fraudulent intent are discussed in sufficient detail for defendants to respond to the allegations. Id. (Section of Complaint entitled "The False and Misleading Nature of the Public Statements" chronicles defendants' actions and explains how those actions adversely affected plaintiffs).

2. Failure to Plead Scienter with Specificity

An part of their urging the court to dismiss this action under Rule 90)), defendants argue that plaintiffs have not adequately pleaded the scienter requirement of a securities fraud claim.

Defendants contend that because plaintiffs have not demonstrated that defendants had any fraudulent intent when they made the allegedly misleading statements concerning SDG's financial status, their complaint should be dismissed pursuant to Rule 9(b).

Scienter is an element of the plaintiffs, claims under Section 10(b) of the Securities and Exchange Act of 1934, 15 U.S.C. § 78j(b) and Rule 10b-5 of the Securities and Exchange Commission ("SEC"). Ernst & Ernst. v. Hochfelder, 425 U.S. 185, 193 (1976), reh'g denied, 425

U.S. 986 (1976). To satisfy the scienter requirement, plaintiffs here must demonstrate that the defendants at least acted with reckless conduct when they reported the allegedly false statements. See Herm v. Stafford, 663 F.2d 669, 684 (6th Cir. 1981). The Complaint itself must "allege material misstatements or omissions indicating an intent to deceive or defraud". Auslender v. Energy Management Corp., 832 F.2d 354, 356 (6th Cir. 1987).

> Paragraph 115 of the Complaint alleges that:
>
> Defendants, pursuant to the plan, scheme and unlawful course of conduct, knowingly and recklessly issued, caused to be issued, participated in the issuance of deceptive and materially false and misleading statements to the investing public which were contained in or omitted from various documents, including documents filed with the SEC, and various other statements, as particularized above.

Paragraph 116 of the Complaint further alleges that defendants' reckless and/or intentional conduct in issuing misleading statements "adversely affect [ed] the integrity of the market in SDG common stock." Further, although setting forth a defendant's motive to defraud is insufficient in and,of itself to satisfy Rule 9(b), it is a circumstance that can be considered in determining whether scienter has been properly pleaded. Ballan v. Upjohn Co., 814 F. Supp. 1375, 1387 (W.D. Mich. 1992). Paragraph 117 states that

the defendants' scienter can be inferred from "their sale of common stock during the Class Period" because the individual defendants and SDG profited through their significant financial gains during the Class Period. See Rubinstein v. Collins, 20 F. 3d 160, 169 (5th Cir. 1994) ("Insider trading in suspicious amounts or at suspicious times is, of course, presumptively probative of bad faith and scienter."); In re Apple Computer Sec. Litig., 886 F.2d 1109 (9th Cir. 1989), cert. denied, 496 U.S. 943 (1990). In determining whether scienter has been properly pleaded, the court must consider that under Rule 9(b) "[m]alice, intent, knowledge, and other condition of mind of a person may be averred generally." Further, the principle of balancing Rule 9(b) with Rule 8(a) discussed earlier applies equally to the court's analysis of the scienter issue. Thus, in considering those two principles in conjunction with the standard for pleading scienter set forth in Auslender, as well as the paragraphs already cited from the Complaint, the court finds that plaintiffs, have satisfied Rule 9 (b) with respect to pleading scienter. Additionally, the question of scienter, which requires an analysis of defendants' intent and conduct, is one that is ordinarily and most appropriately reserved for the finder-of-fact. In re Rospatch Sec. Litig., 760 F. Supp. 1239, 1253 (W.D. Mich. 1991).

In reaching its conclusion on defendants' motion to dismiss pursuant to Rule 9 (b) , the court has been guided by the underlying purpose of Rule 9(b): to provide the

defendants with adequate notice of their alleged violations so that they can craft an effective response to the allegations contained in the Complaint. See American Town Center v. Hall 83 Associates, 912 F.2d 104, 109 (6th Cir. 1990) (Rule 9(b) only requires that plaintiffs plead sufficient facts to give defendants adequate notice of alleged wrongdoing so that defendants can prepare responsive pleadings). After careful consideration of plaintiffs' Complaint, the court finds that plaintiffs' have provided defendants with adequate notice of the substance of their claims against them. Accordingly, defendants' motion to dismiss under Rule 9(b) for failure to plead fraud in Count 1 with particularity is denied.

B. Motion to Dismiss for Failure to State a Claim Under Rule 12(b)(6)

The purpose of a Rule 12 motion is to test the sufficiency of the pleadings. Davis H. Elliot Co. v. Caribbean Utilities Co., 513 F.2d 1176, 1182 (6th Cir. 1975). When considering such a motion, the court is required to liberally construe the complaint and take its well-pleaded facts as true. Id. The motion "should not be granted 'unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" Id. (quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). Further, the Sixth Circuit has clarified that "a judge may not grant a Fed. R. Civ. P. 12 (b) (6) motion to dismiss based on a disbelief of

a complaint's factual allegations." In re Delorean Motor Co., 991 F.2d 1236, 1240 (6th Cir. 1993).

1. Failure to Allege A Legally Cognizable Untrue Statement or Relevant Omission

Defendants claim that plaintiffs "attempt to concoct a fraud case where none exists." To support that contention, defendants argue that plaintiffs' Complaint does not set forth any examples of fraudulent statements made by defendants or any omissions where defendants had a duty to disclose relevant information. 17 C.F.R. § 240.10h)-5 of the Securities and Exchange Commission entitled "Employment of Manipulative and Deceptive Devices" provides in pertinent part:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any national securities exchange,
>
> > (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make -the statements made, in the light of the circumstances under which they were made, not misleading,

Id. Thus, to state a cause of action under the federal securities laws, the Complaint must contain allegations that defendants, made untrue statements of material facts or failed. to state a material

fact where there was a duty to disclose such fact. Defendants contend that plaintiffs cannot point to any affirmative statement that was false or misleading when made or as to which prompt correction was "necessary to make" that affirmative statement "not misleading." Defendants argue that none of their allegedly fraudulent statements are actionable because they consist of "accurate statements of current performance or past earnings, statements of optimism, reasonably held honest opinions, and third party statements for which defendants cannot be held liable under the federal securities laws." Conversely, plaintiffs allege that defendants made false or misleading statements regarding SDG's financial health in contravention of the federal securities laws, Specifically, plaintiffs claim that defendants should have disclosed the following to the public: (1) that SDG was illegally marketing and promoting its products for pedicile use that had not been cleared or approved by the FDA, (2) that a material percentage of SDG's reported earnings were attributable to alleged "illegal price gouging" on loaner sets, and (3) that NMS would be unable to meet its second quarter 1994 purchase commitment and that defendants had already decided to terminate them as a distributor.

To set forth a fraud action based on the federal securities laws, plaintiffs must demonstrate that a "particular statement, when read in light of all the information then available to the market, or a failure to disclose particular

information, conveyed a false or misleading impression." In re Convergent Technologies Sec. Litig., 948 F.2d 507, 512 (9th Cir. 1991); see In re Donald J. Trump Casino Sec. Litig., 793 F. Supp. 543, 556 (D. N.J. 1992) ("[T]he context of an allegedly false and misleading statement is a crucial consideration."). Although "[s]olitary statements alone cannot support a federal securities law claim when read out of context," Trump, 793 F. Supp. at 556, "some statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors." Convergent Technologies, 948 F.2d at 512. Such "misleading statements" or "half-truths' are actionable. See Howing Co. v. Nationwide Corp., 826 F.2d 1470, 1481 (6th Cir. 1987), cert. denied, 486 U.S. 1059 (second clause of 10b-5 addresses "half-truths" rather than omissions per se); Nagel v. First of Michigan Corp., 784 F. Supp. 429, 435 (W.D. Mich. 1991) (omission is actionable if failure to disclose renders the information reported a "half-truth"); Greenfield v. Professional Care, Inc., 677 F. Supp. 110, 113-114 (E.D.N.Y. 1987) (finding actionable defendants "accurate" earnings statement because statement failed to disclose that portion of earnings reflected illegally obtained payments).

Plaintiffs do not contend that the information reported by SDG, such as hard financial date, or the statements made, were literally untrue, but that they were not the whole truth because other information was not

reported that would have reflected an underlying basis for the financial data other than business as normal.

Thus plaintiffs states:

> As the Complaint alleges, the market was unaware that the Company's purported success had been built, in significant part, on an unstable and uncertain foundation of illicit sales and billing practices, which could end at any time, robbing the Company of a large percentage of its future sales and potentially exposing it to stringent FDA penalties.

Pls.' Memo. of Law in Opp. to Defs.' Mot. to Dismiss at 14. While plaintiffs do assert that the true hard data were misleading because it was not revealed that these figures were not derived from normal business development, but from unreported activities, the crux of the claim is that certain material information was not reported or revealed to the public.[1] Investors, of course, would like to have any material information, but they are not entitled to all information that might somehow be of some assistance to them in predicting the future of the stock. The fact that the

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[1] Plaintiffs themselves admit that "the instant case, for the most part, revolves around defendants' egregious failure to disclose the material facts . . . ." Pls.' Memo. of Law in Opp. to Defs.' Mot. to Dismiss at 13.

information might somehow give more detail to the earning history reported is not alone a basis to require disclosure.

The facts alleged in the Complaint, as opposed to the conclusions asserted, do not reflect that the public statements and filed reports were false. The Complaint does, however, allege that certain "facts" which the defendants failed to disclose were necessary to keep the statements and reports from being misleading.

Omissions are only actionable where defendants have a duty to disclose the information at issue. See Basic, Inc. v. Levinson, 485 U.S. 224, 239 n.17 (1988) ("Silence, absent a duty to disclose, is not misleading under 10b-5"); Chiarella v. United States, 445 U.S. 222 (1980). To establish a duty to disclose, plaintiffs must first show that the information they claim was fraudulently withheld was "material." Materiality exists "if there is a substantial likelihood that, under all the circumstances, the information would have assumed 'actual significance in the deliberations of the reasonable shareholder.'" TSC Industries, Inc. v. Northway, 426 U.S. 438, 449 (1976); see S.E.C. v. Blavin, 760 F.2d 706, 711 (6th Cir. 1985) (relying on essentially same "materiality" standard as the TSC Court).

Once materiality is established, a duty to disclose such material information arises only in certain delineated circumstances. See Chiarella, 445 U.S. at 235 (distinguishing between concepts of materiality and duty to disclose); Starkman v. Marathon Oil Co., 772 F.2d 231, 238

(6th Cir. 1985), cert. denied, 475 U.S. 1015 (1986) ("Duty to speak must exist before the disclosure of material facts is required under Rule 10b-5."). The courts have delineated three instances where a duty to disclose arises. The first is where a corporate insider uses material non-public information to profit financially in the securities market. Chiarella, 445 U.S. at 226-230. The second is where a company omits material information in a report it must file pursuant to a particular statute or regulation. See Roeder v. Alpha Industrial, Inc., 814 F.2d 22, 26-27 (1st Cir. 1987). The third is when defendants have made a public statement, and further disclosures are necessary to "make the statements made . . . not misleading." Rule 10b-5, 17 C.F.R. § 240.10b-5; Howing, 826 F.2d at 1481.

Here, defendants contend that plaintiffs have failed to allege any facts that would support the inference that the statements contained in the Complaint were false when made. Defendants argue in the alternative that even if plaintiffs have sufficiently alleged that defendants made certain misrepresentations or failed to inform the public of certain facts, they were under no duty to disclose the information plaintiffs claim caused their injury. Conversely, plaintiffs argue that the Complaint specifically alleges that SDG's growing revenues and earnings were merely the fruits of SDG's unlawful and improper marketing and billing practices which would not have been achieved but for defendants' improper conduct. Plaintiffs further contend

that defendants had a duty to disclose the alleged material information at issue because insider trading was taking place and defendants also had a duty to supplement public statements already reported in order to ensure they were not misleading the public.

Most particularly the Complaint alleges that three items of material information were not reported which information was necessary to keep otherwise true data from being misleading.

a. Illegal Promotion of SDG Products for Pedicile Use

Plaintiffs contend that defendants fraudulently created the impression that SDG's revenue and earnings growth was due to an increase of legitimate unit sales of SDG products instead of the illicit promotion of its products for use in the pedicile area of the spine. To support their allegations, plaintiffs rely on various affirmative statements about SDG's financial growth as well as omissions where plaintiffs contend defendants had a duty to disclose relevant information.

Plaintiffs' Complaint alleges that "[d]efendants were aware during the Class Period that much of SDG's sales success had been due to SDG's illicit promotion of its products for use in the pedicile area of the spine," Pls.' Compl. ¶ 72, and that "defendants' intentional failure to disclose those facts caused SDG common stock to be traded at artificially inflated prices during the Class Period." Pls.'

Compl. ¶ 73. Paragraphs 74-77 of the Complaint assert that the FDA never approved SDG's use of screws in the pedicile of the spine and explain that without that approval SDG was prohibited from promoting its products for pedicile fixation. However, plaintiffs contend in ¶¶ 77-80 and 88-91 that despite the FDA's restrictions, defendants fraudulently circumvented the law by sponsoring seminars and other like programs to promote the use of pedicile screws for spinal surgery and consequently improve that financial position of SDG. Paragraphs 81-85 of the Complaint cite to various correspondence between the FDA and SDG where the FDA warns SDG that it does not have authorization to sponsor programs promoting use of pedicile screws in spinal surgery. The Complaint further alleges that despite the FDA's repeated warnings, defendants "engaged in a pervasive effort to promote the screw" for pedicile fixation. Id. at ¶ 86. After setting out the above allegations, plaintiffs claim that defendants' statements during the Class Period were material misrepresentations and omissions because they failed to disclose that a significant part of SDG's sales were due to the illegal promotion of the pedicile screws as described in the Complaint. Id. at ¶¶ 92, 96.

Defendants dispute plaintiffs' allegations that SDG did not disclose that pedicile screws were not FDA approved for promotion by SDG. Defendants cite to SDG's 1991 Prospectus and its 1992 Form 10-K where defendants

purportedly discuss FDA's non-approval of pedicular fixation and the potential implications of that non-approval for SDG.[2] Defs.' Mot. to Dismiss pp. 11-14.

The plaintiffs' Complaint does not contain any valid allegations of affirmative misstatements issued by defendants. Although plaintiffs claim that "half-truths" and omissions create liability for the defendants in this action, plaintiffs have failed to demonstrate to the court that defendants had a duty to disclose that information in order to keep the statements made or reports filed from being misleading. Although the allegedly "omitted" information may have assumed some significance in the deliberations of

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[2] Plaintiffs argue that defendant's incorporation of such documents in its motion to dismiss should convert defendants' motion into a motion for summary judgment. See Fed. R. Civ. P. 12(b) (where a motion to dismiss relies on matters outside the pleadings, that motion should be converted into a motion for summary judgment). The court finds that notwithstanding defendants' citation to documents outside the pleadings, the court can properly consider public disclosure documents without converting the instant motion into a motion for summary judgment. See Kramer v. Time-Warner Inc., 937 F.2d 767, 773 (2d Cir. 1991) (court could consider public documents filed with the SEC but not attached to complaint on motion to dismiss); Steiner v. Shawmut Nat'l Corp., 766 F. Supp. 1236, 1241 n.13 (D. Conn. 1991) (rejecting argument that newspaper articles could not be considered on motion to dismiss securities fraud suit).

the reasonable shareholder, defendants had no duty to disclose it.

Plaintiffs have attempted to create a duty by alleging that the individual defendants traded illegally on insider information; however, plaintiffs have not brought an insider trading claim against the defendants. Thus, the court declines to accept plaintiffs' argument that the allegations of insider trading create a duty that is transferable to the securities fraud claim against the corporate defendant or the individual defendants. See In re Seagate Technology, 843 F. Supp. 1341, 1369 (N.D. Cal. 1994) (recognizing that "importing this duty to disclose" would result in potentially "enormous liability on insider traders-liability that could not have been anticipated by Congress").

Plaintiffs' Complaint also does not create a duty to disclose with respect to the allegations that defendants violated the securities laws by issuing misleading statements or failing to report material information. With respect to plaintiffs' contentions that defendants were violating FDA regulations, "[t]he law does not impose a duty to disclose uncharged, unadjudicated wrongdoing or mismanagement." Ciresi v. Citicorp, 782 F. Supp. 819, 823 (S.D.N.Y. 1991), aff'd, 956 F.2d 1161 (2d Cir. 1992). Even if SDG was involved in illegal activity, such activity does not necessarily give rise to a duty to disclose the corporation's conduct. See In Re Par Pharmaceutical, Inc. Sec. Litig., 733 F. Supp. 668, 678 (S.D.N.Y. 1990) (holding that

defendants did not have a duty to disclose all possible consequences that could have resulted from its alleged bribery of FDA officials); Roeder v. Apha Indus., Inc., 814 F.2d 22 (1st Cir. 1987) (corporation did not have duty to disclose that it had paid bribe to obtain subcontracts for defense work); Greenstone v. Cambex Corp., 777 F. Supp. 88 (D. Mass. 1991), aff'd, 975 F.2d 22 (1st Cir. 1992) (no duty to disclose alleged illegal practices); Crouse-Hinds Co. v. Internorth, Inc., 518 F. Supp. 416, 475 (N.D.N.Y. 1980) (defendants did not have a duty to disclose contingent violations of environmental laws).

The cases cited by plaintiffs for the most part involved a failure to disclose criminal or other similar proceedings that had already occurred. Tapken v. Brown, [1992] Fed. Sec. L. Rep. (CCH) para. 96,805 at 93,116 (S.D. Fla. 1992) (guilty pleas); Greenfield v. Professional Care, Inc., 677 F. Supp. 110 (E.D.N.Y. 1987) (Medicare fraud indictments); SEC v. Jos. Schlitz Brewing Co., 452 F. Supp. 824, 830 (E.D. Wisc. 1978) (bribes). In the case at bar SDG reported, according to the Complaint, that it was not allowed to promote the product for certain use and that the FDA had issued to the Company and others warnings to that effect. Plaintiffs would have the defendants charge and convict the Company of regulatory misconduct which it does not admit and the regulatory agency has not charged. To the extent that these cases support a general argument that a reporting company must report the detail of its

business practices, and presumably confess a violation in the face of a regulatory warning about its business practices, the court declines to follow them. Detailed management decisions about what practices constitute promotion and what do not is not information necessary to keep the reported financial information and statements from being misleading.

Thus, a duty to disclose is not established on account of defendants' failure to report its alleged violations of FDA regulations through its promotion and marketing of pedicile screws.

Even assuming that defendants did violate FDA regulations (and the Complaint is particularly deficient in that specific), it would be impossible for defendants to predict whether the FDA would bring any action against SDG and what the potential ramifications of such action might be.[3] Thus, defendants could not have been expected

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[3] Additionally, the lack of any FDA involvement in this case forces this court to question whether it is the appropriate forum for resolution of this dispute or whether it would be better left to the FDA. See SEC v. Helicopter Indus. Inc., No. 79-C-0469 (N.D. Ill. January 18, 1980) (finding that "[s]ubject matter jurisdiction of this action is premised on a violation of the securities laws, not the banking laws . . . . [I]n the absence of an adjudicated finding of illegality of [the challenged banking] transaction, the Court is not at liberty to assume or make its own finding of such illegality.").

to report the "possibility" of adverse FDA action against the,. In Re Par Pharmaceutical Sec. Litig., 733 F. Supp. at 678 (finding that defendants could not be held liable for failing to disclose "what would have been pure speculation."). Finally, many of plaintiffs' allegations appear to target defendants' management decisions and activities. Such claims are not the province of federal securities action, but rather fall within the purview of state law principles regarding fiduciary duty and corporate governance.

b. Loaner Sets

Plaintiffs' Complaint similarly alleges that a great deal of its economic growth was related to sales from SDG's loaner sets which plaintiffs claim were excessively priced. Pls. I Compl. ¶ 97. The Complaint states that SDG was charging extremely high premiums on its loaner sets which were often "100% over the regular list price". Id. at ¶ 98. Paragraph 99 of the Complaint claims that defendants knew that "its loaner set premiums of 100% constituted improper price gouging." Id. at ¶ 99. Plaintiffs allege that profits derived from premiums from the loaner sets increased 1000% between December 1991 and March 1994 and that such an increase demonstrates a "substantial focus [by SDG] on loaner sets." Id. Plaintiffs contend that: when the purchasers recognized the higher cost involved in the use of loaner sets, some refused to continue purchasing under the loaner program. The Complaint cites to various

statements by SDG where plaintiffs claim SDG "misled the market into believing that the practice did not really help SDG's bottom line." Id. at ¶ 101. Such statements regarding the significance of the premiums charged for the loaner sets, detailed in ¶¶ 101, 102, 104, and contained in company reports and issued by directors of SDG, allegedly created a misleading impression of SDG's financial status.

The court finds that defendants' motion to dismiss on the loaner set issue is also well-taken. As plaintiffs concede, defendants did acknowledge in SDG's May 16, 1991 Prospectus that loaner sets were charged out a premium price. Pls.' Mem. of Law in Opp. to Defs.' Mot. to Dismiss at 19. Further, SDG did not have a duty to disclose the information contained in plaintiffs' Complaint. The federal securities laws do not contain a duty to disclose allegedly high markups on a corporation's merchandise that may later create a decline in corporate revenue. Further, the conclusion that buyers will later decide not to pay the same high premiums for the loaner sets is a mere forecast and does not provide the factual support necessary to sustain plaintiffs' Complaint. See Hanon v. Data Products Corp., 976 F.2d 497, 506 (9th Cir. 1992) ("Discussion amongst management staff regarding potential action to be take sometime in the distant future is not an item appropriately made a part of a public disclosure because of its speculativeness."); In Re Par Pharmaceutical 733 F. Supp. at 678 (finding that defendants could not be held

liable for failing to disclose "what would have been pure speculation."). Even if SDG management knew that the higher priced loaner sets would sooner or later have to be reduced in price or that the market might dissipate, such speculation is not necessary to keep the true facts reported and statements made from being misleading. Moreover, the actual prices of the loaner sets is a detail hardly necessary to informed decision making. "A company 'need not detail every corporate event, current or prospective . . . .'" In re Convergenet Technologies Sec. Litig., 948 F.2d 507, 516 (9th Cir. 1991) (quoting from Marx v. Computer Sciences Corp., 507 F. 2d 485, 491 (9th Cir. 1974)). Accordingly, for the reasons discussed above, in addition to the principles articulated in the preceding section regarding pedicile screws, the court grants defendants' motion to dismiss on plaintiffs' loaner set claim.

C. NMS' Inability to Meet its Second Quarter Commitment

The Complaint alleges that defendants knew that its principal distributor NMS would not be able to meet its second quarter purchase commitment at least one month in advance of SDG publicly announcing that fact. Pls.' Compl. ¶ 107. Plaintiffs, Complaint further states that SDG "knew well before the end of the Class Period that SDG would likely terminate NMS' distribution contact." Id. at ¶ 107. Additionally, plaintiffs claim that SDG waited until June 1994 to announce "the termination of NMS' distribution

rights, the purchase of NMS' Sofamor products inventory and the start of SDG's direct sale of Sofamor products" even though defendants had been planning such changes in the company for "some time." Id. at 110. Plaintiffs allege that SDG's financials were negatively impacted on account of the "NMS sales problems and termination of the NMS contract." Id. at ¶ 111.

Plaintiffs' primary complaint regarding the NMS situation is that defendants should have reported their plans to terminate NMS. However, plaintiffs cite very few, if any, facts to support that contention. Defendants are not required to disclose they are considering terminating a distributor because such deliberations fall within the purview of" a business judgment that is best left to the corporation. Additionally, defendants did not have a duty to disclose the potential repercussions of that termination because such information would have been merely speculative. See infra p. 21 (discussing that a corporation does not have a duty to speculate about future changes in its financial status); Arazie v. Mullane, 2 F.3d 1456, 1468 (7th Cir. 1993) (finding that firms are not required to publish in-house estimates of their future performance). Additionally, even if such a decision amounted to mismanagement, defendants still had no duty to report the information. See Ciresi, 782 F. Supp. at 823. Therefore, after carefully reviewing plaintiffs' Compiaint, the court finds that plaintiffs' have not established that defendants, had a duty to disclose their

discussion and negotiations with NMS. For that reason, the court grants defendants' motion to dismiss on this issue.

In conclusion, plaintiffs cannot state a claim against defendants simply by referring to various instances where defendants failed to disclose material information, without further demonstrating to the court that defendants had a duty to disclose that information. The admittedly true statements made and reports filed by SDG cannot be shown to have been misleading by reason of the defendants, failure to disclose the three areas of information alleged in the Complaint. Because plaintiffs have failed to satisfy the "duty to disclose" requirement which is a prerequisite to any securities fraud claim, the court grants defendants' motion to dismiss with respect to plaintiffs' federal claims.[4]

2. Plaintiffs Fail to State a Claim for Common Law Fraud and Negligent Misrepresentation

Defendants move to dismiss plaintiffs' state law claims on the ground that plaintiffs have not sufficiently plead the reliance requirement for common law fraud and negligent misrepresentation. Defendants argue that plaintiffs do not plead actual reliance on the defendants' alleged misstatements or relevant omissions, but rather invoke the "fraud on the market" theory to trigger the presumption of

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[4] The court declines to address the issue of control person liability as the granting of defendants' motion to dismiss on the substantive federal fraud claim renders. the control person question moot.

reliance. Because defendants contend that the "fraud on the market" theory only applies to federal securities claims, they argue that plaintiffs, state claims should be dismissed pursuant to Rule 12(b)(6). Plaintiffs respond that the Complaint does plead actual reliance and that even if it did not, the "fraud on the market" theory is applicable to state claims.

To establish a claim. for common law fraud or negligent misrepresentation under Tennessee law, actual reliance must be proven. Williams v. Van Hersh, 578 S.W.2d 373, 376 (Tenn. App. 1978), cert. denied, (1979) (reasonable reliance is an element of positive fraud); Tartera v. Palumbo 453 S.W.2d 780 (1970) (reliance required to prove negligent misrepresentation); Milwee v. Peachtree Cypress Investment, 510 F. Supp. 284, 288 (1978), aff'd, 644 F.2d 885 (6th Cir. 1978) (Under Tennessee law, "reasonable reliance by the plaintiff on the misrepresented fact" is an element of the common law tort of fraud and misrepresentation and such misrepresentations must be made directly to the plaintiff). Thus, to survive a 12 M (6) motion, plaintiffs must plead actual reliance on defendants' alleged fraudulent activity.

Plaintiffs contend that paragraph 125 of their Amended Complaint pleads actual. reliance by stating:

> At the time of such misrepresentations and omissions of material facts, plaintiffs were ignorant

> of their falsity and believed them to be true. Plaintiffs relied upon the superior knowledge and expertise of defendants and justifiably relied to their detriment on the misrepresentations and omissions of defendants to the market. Had the plaintiffs and the Class been aware of the true facts, they would not have purchased SDG common stock at all, or at the prices they paid.

(emphasis added). Defendants argue that the paragraph supposedly alleging reliance is deficient because it invokes the classic "fraud on the market" theory without pointing out the specific material omissions or misrepresentations made directly to and relied upon by the individual plaintiffs.

Plaintiffs' crafting of paragraph 125 of the Complaint sets forth a theory of reliance that is the functional equivalent of the "fraud on the market" doctrine. The Complaint does not plead actual reliance of the individual plaintiffs on representations made directly to them, but instead on representations made by the defendants to the market. Therefore, the question before the court on plaintiffs, state law claims is whether or not the presumption afforded by a "fraud on the market" theory for federal securities actions applies similarly to state fraud actions.

In Levinson, the Sixth Circuit adopted the "fraud on the market theory" which recognizes a rebuttable

presumption of reliance in securities fraud cases where the plaintiffs can prove the following five elements:

(1) that the defendants made public misrepresentations;

(2) that the misrepresentations were material;

(3) that the stock was traded on an efficient market;

(4) that the misrepresentations would induce a reasonable, relying investor to misjudge the value of the stock; and

(5) that the plaintiff traded in the stock between the time the misrepresentations were made and the time the truth was revealed.

Levinson v. Basic, Inc., 786 F.2d 741, 750 (6th Cir. 1986), vacated on other grounds, 485 U.S. 224 (1988).[5] However, the Supreme Court has held that federal securities claims are distinct "from common law deceit misrepresentation claims." Levinson, 485 U.S. at 243 n.22. Consequently, several federal courts have declined to adopt a "fraud on the market" theory of reliance for state fraud

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[5] Levinson was vacated on other grounds by the Supreme Court which noted that elements 2 and 4 may be merged. 485 U.S. at 228 n.27. The stated elements have since been reaffirmed in Freeman v. Laventhol & Horwath, 915 F.2d 193, 197(6th Cir. 1990) . Any merger of elements is irrelevant for the issue at hand.

actions. See K. Peil v. M. Speiser, 806 F.2d 1154, 1163 n.17 ("While the fraud on the market theory is good law with respect to the Securities Acts, no state courts have adopted the theory, and thus direct reliance remains a requirement of a common law securities fraud claim."); Rosenberg,M.D. v. Digilog, 648 F. Supp. 40, 43 (E.D. Pa. 1985) ("Both causes of action require proof of reliance on defendants" representations and my research reveals no state court decisions which have adopted a 'fraud on the market' type theory of reliance."). Most significantly, no federal court has adopted the theory under Tennessee law and the Tennessee courts have never ruled on the issue.

Nevertheless several federal courts have held that even though their respective state courts had not ruled on the availability of a "fraud on the market" theory to common law fraud, that dearth of legal precedent did not obligate the federal court to dismiss the state fraud claim.[6]

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[6] See Minepco v. Hunt, 718 F. Supp. 168, 176 (S.D.N.Y. 1989) ("[I]t does not necessarily follow that, because the Supreme Court has stated in dicta that the securities laws add to the protections of common law fraud . . . . In the absence of binding authority to the contrary, I am not persuaded, although I recognize that the question is open, that the New York courts would not adapt the doctrine of common law fraud to encompass the defendants' manipulation of fraud in this case. Hurley v. Federal Deposit Ins. Corp., 719 F. Supp. 27, 34 n.4 (D. Mass. 1989) ("While no Massachusetts case has yet endorsed the

This court disagrees with that reasoning and has always been reluctant to decide novel issues of state law in the absence of guiding precedent from the Tennessee state courts. See e.g. Valley Products v. HFS , 877 F. Supp. 1087, 1094 (W.D. Tenn. 1994) (declining to find a cause of action for intentional interference with prospective economic advantage where state courts had never recognized the tort, although they had also never expressly rejected it). Because the Tennessee courts have never adopted the "fraud on the market" theory to establish the element of reliance in fraud actions, this court declines to create new Tennessee law. See United Mine Workers v. Gibbs , 383 U.S. 715, 726 (1966) ("Needless decisions of state law should b-:- avoided both as a matter of comity and to promote justice between the parties by procuring for them a surer-footed reading of applicable law."). For those reasons, the court grants defendants' motion to dismiss on

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fraud on the market theory in a common law fraud context, neither has any court rejected that theory. The issue has simply never before been presented for a decision. This court believes that, if the Supreme Judicial Court were faced with the question, it would recognize the fraud on the market theory as a substitute for pleading reliance . . . . "); In re Atlantic Financial Fed. Sec. Litig., 1990 U.S. Dist. LEXIS 14807, at *5 (E.D. Pa. Oct. 30, 1990) (holding that plaintiffs may use "fraud on the market" theory to establish reliance even though Pennsylvania courts had not yet ruled on the issue).

plaintiffs' state claims fraud and negligent misrepresentation.

CONCLUSION

For the reasons articulated above, the defendants' motion to dismiss with prejudice is hereby anted in its entirety.

IT IS SO ORDERED this 30th day of September 1995.

/s/ Jerome Turner
Jerome Turner
United States District Judge

APPENDIX D

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

JUDGMENT

Civil Case Nº. 94-2303-TUA
Filed November 6, 1995 at 12:00 a.m.

Pages D-1 thru D-1

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

FILED
95 NOV 6

IN RE	:	
SOFAMOR DANEK GROUP, Inc.	:	
	:	**Civil Action Nos.**
	:	**94-2303 TU**
	:	**94-2346 TU**
THIS DOCUMENT RELATES TO	:	**94-2418 TU**
ALL ACTIONS	:	**94-2519 TU**
	:	

JUDGMENT

Decision by Court. This action came for consideration before the Court. The issues have been duly considered and a decisions has been rendered.

IT IS ORDERED AND ADJUDGED that the above consolidated actions are dismissed with prejudice, in accordance with the Order on Defendants' Motion to Dismiss docketed October 5, 1995.

APPROVED:

/s/ Jerome Turner
JEROME TURNER
UNITED STATES DISTRICT JUDGE
/s/ Tracy Wherry
(By) DEPUTY CLERK

This document entered on docket sheet in compliance with Rule 58 on 11/5/95

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

PETITION FOR REHEARING
AND SUGGESTION FOR REHEARING *EN BANC*

Sixth Circuit Case Nº. 95-6491/6592
Filed August 28, 1997

Pages E-1 thru E-17

Nos. 95-6491/6592

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

In Re: SOFAMOR DANEK GROUP, INC.

filed
Aug. 28 '97

BRUCE G. MURPHY, RANDY OWEN, MARY KENNEDY, and LYNDA KRAMER,

Plaintiffs-Appellants,

MIKE ROBERTS,

Plaintiff,

v.

SOFAMOR DANEK GROUP, INC., E. RON PICKARD, LAURENCE Y. FAIREY, LEANDER D. BEARD, GEORGE F. RAPP, MILES D. IGO, ALAN J. OLSEN, YVES PAUL COTREL, and PHILLIPE COTREL,

Defendants-Appellees.

On Appeal from the United States District Court
For The Western District of Tennessee
at Memphis

Petition For Rehearing and
Suggestion for Rehearing *En Banc*

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TABLE OF CONTENTS

Page(s)

I. Required Statement for Rehearing *En Banc* 1

II. Introduction 2

III. Purpose of Petition 2

IV. Grounds For Rehearing 4

A. The SDG Investors Have a Cognizable Claim Under the Federal Securities Law Based On Sofamor Danek's Affirmative False Statements 4

B. The Information Sofamor Danek Wrongly Omitted to Disclose Was Not Whether The Company's Promotional Activities Were Illegal, But the Fact That It Was Engaged in the Promotional Activities Themselves 9

V. Conclusion 14

VI. Certificate of Service 15

PETITION FOR REHEARING AND SUGGESTION FOR REHEARING EN BANC

In The United States Court of Appeals For The Sixth Circuit

I. Required Statement For Rehearing En Banc

I express a belief, based on a reasonable and studied professional judgment, that the panel decision is contrary to the following decision(s) of the Supreme Court of the United States, and the United States Court of Appeals for the Sixth Circuit, and the consideration by the full Court is necessary to secure and maintain uniformity of decisions:

Basic, Inc. v. Levinson, 485 U.S. 224 (1988); and

Aschinger v. Columbus Showcase Co., 934 F.2d 1402 (6th Cir.1991).

These cases recognize that under § 10(b) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder, a claim may be grounded upon an affirmative misrepresentation.

I express a belief, based on a reasoned and studied professional judgment, that this appeal involves one or more questions of exceptional importance:

1. This appeal involves the law of disclosure as it relates to publicly owned and traded companies, which strikes at the heart of investor confidence in and the integrity of our national capital markets.

II. INTRODUCTION

The plaintiff-appellants (hereinafter, "SDG Investors"), by counsel,petition this Honorable Court for are hearing pursuant to Rule 40, F.R.A.P., and a Suggestion for Rehearing En Banc pursuant to Rule 35, F.R.A.P. and Local Rule 14. This Petition relates to the recommended published opinion filed August 14, 1997, by a panel of this Court, a copy of which is attached.

III. PURPOSE OF PETITION

The SDG Investors file this petition to request reconsideration of the affirmance by a panel of this Court of the District Court's order dismissing with prejudice their Consolidated Amended Class Action Complaint ("Complaint"), which alleged violations of the federal securities laws and pendent state law claims. The SDG Investors respectfully contend that the panel's opinion overlooked certain facts and law, and mistakenly misinterpreted and misapplied other facts and law. Specifically, the panel:

1. Overlooked the fact that the SDG Investors have a cognizable claim for violation of the federal securities laws based on defendant-appellees, (hereinafter, "Sofamor Danek") *affirmative false statements.*
2. Failed to recognize that once Sofamor Danek chose to make statements on the issue of promoting or encouraging use of its devices as suitable for pedicular attachment (representing that it did not promote the

devices for such use), it necessarily had a duty to disclose the specific promotional activities it actively and undisputedly engaged in.

3. Overlooked the fact that once this duty to disclose was created, even if Sofamor Danek may not have been required to characterize certain material activities in pejorative terms (i.e., characterize their activities as improper or illegal), Sofamor Danek was nevertheless required to disclose *the "hard" facts describing the activities themselves.*

The SDG Investors request reconsideration of the panel to reverse its opinion, find that the SDG Investors' Complaint adequately states cognizable claims under the federal securities laws, and remand this matter to the District Court for further proceedings.

IV. GROUNDS FOR REHEARING

A. The SDG Investors Have A Cognizable Claim Under the Federal Securities Laws Based On Sofamor Danek's Affirmative False Statements

In its August 14, 1997 Opinion ("Panel Opinion"), the Court correctly noted that there are two alternative ways to state a cause of action under § 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b) (the "Exchange Act"), and Rule 10b-5 promulgated thereunder by the SEC:

> To state a cause of action under § 10(b) and Rule 10b-5 a plaintiff must plead that the defendant made (1) a false

statement, or [2] omitted to state a material fact which should have been disclosed ....

Panel Opn. at 11 (emphasis added) (citations omitted). Unfortunately, the analysis conducted by the Court completely overlooked the first alternative for pleading a federal securities law claim: by alleging that the defendant made a false statement. Based on the undisputed facts of this case, it was here that the Court first erred.

The following facts are undisputed:[1]

1. Sofamor Danek produced and marketed the Danek Bone Plate and Screw Product Line in the U.S., which, as medical devices, were regulated by the FDA.

2. The Bone Plate and Screw Product Line had only gone through the FDA's "§510(k) notification" procedure. The §510(k) notification procedure is essentially a *quid pro quo* arrangement, where the FDA approves eligible devices for limited, pre-existing uses, without requiring the more onerous and time-consuming "pre-market approval" process. In return, device manufacturers are limited to marketing and Labeling of the device for recognized, pre-existing uses of the device.

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[1] It is uniformly recognized that on a motion to dismiss, all pleaded facts, as well as all favorable inferences reasonably deducible therefrom, are deemed true. *See, e.g., Sinay v. Lamson & Sessions Co.*, 948 F.2d 1037, 1039-40 (6th Cir. 1991).

3. In 1990, the FDA advised medical device manufacturers, including Sofamor Danek, that using bone plates, sacral screws, etc. (*i.e.*, Sofamor Danek's Bone Plate and Screw Product Line) for pedicular attachment (a.k.a., inter pedicular segmental fixation) was not a recognized, preexisting use of the devices, but rather constituted an unapproved "new use."

4. In accordance with FDA regulations, therefore, *Sofamor Danek was prohibited from labeling, promoting, or -in any way encouraging the use of its Bone Plate and Screw Product Line as suitable for pedicular attachment.*

5. Although Sofamor Danek was prohibited from labeling, promoting or encouraging the use of its Bone Plate and Screw Product Line as suitable for pedicular attachment, under the "medical judgment" rule a physician could choose to USE! the devices for pedicular attachment if the physician deemed it to be in the patient's best interest.

6. Sofamor Danek made several affirmative statements unequivocally representing that it did **not** promote or encourage the use of its Bone Plate and Screw Product Line as suitable for pedicular attachment.

7. Notwithstanding its several unequivocal public statements to the contrary, in truth Sofamor Danek used both surreptitious and open means to promote and encourage t-he use of its Bone Plate and Screw Product Line as suitable for pedicular attachment.

(*See infra*, pp. 12-13.)

Additionally, in light of the above *undisputed* facts, the following is *indisputable* fact:

8. Each and every time Sofamor Danek unequivocally and publicly stated it did not encourage the use of its Bone Plate and Screw Product Line as suitable for pedicular attachment, Sofamor Danek *made an affirmative factual misrepresentation.*

As long as the false statements were material, they form an adequate basis to support, a §10(b) and Rule lob-5 claim. These false statements were clearly material, and, in fact, materiality has never been seriously challenged.

A false statement is material if a reasonable investor would have viewed the false information conveyed as "having significantly altered the total mix of information made available." *Basic, Inc. v. Levinson*, 485 U.S. 224, 232 (1988) (internal quotation and citation omitted). *See also Aschinger v. Columbus Showcase Co.*, 934 F.2d 1402, 1410 (6th Cir. 1991) ("[i]nformation is material if it would 'be considered significant to the trading decision of a reasonable investor.'" (quoting *Basic)).* Certainly, the fact that, contrary to its public representations, Sofamor Danek was indeed engaged in activities geared to promoting and encouraging the use of its Bone Plate and Screw Product Line as suitable for pedicular attachment is a fact that any reasonable investor would consider as altering the total mix of information available, or that would be significant to a reasonable

investor's trading decision. Unquestionably, Sofamor Danek relied on sales of its Bone Plate and Screw Product Line for a material portion of its revenues. *See, e.g.,* Complaint, ¶¶ 39, 46 (J.A. at 51-52, 54-55.) In fact, the Company represented that a great deal of its financial success was as a result of "continued growth in the spinal market" and an increased number of spinal implant procedures. *See, e.g.,* Complaint, ¶¶ 39, 43, 50. (J.A. 51-52, 53-54, 56-57.)

Information that would raise serious questions about whether Sofamor Danek was promoting and encouraging Use of its devices as suitable for pedicular attachment, especially in the face of the Company's flat denials, would implicate serious matters of concern for investors. For instance, the fact that Sofamor Danek was promoting and encouraging the use of its Bone Plate and Screw Product Line as suitable for pedicular attachment raises the distinct possibility that Sofamor Danek's activities in doing so violated FDA regulations, which also raises the possibility that Sofamor Danek might have been subject to a number of materially negative consequences, such as an FDA enforcement action with potentially disastrous sanctions, or civil lawsuits by patients whose physicians used the devices for pedicular attachment. As such, any reasonable investor would consider it significant to know of the activities giving rise to such contingencies. In addition, in light of Sofamor Danek's clear representations that it did not promote or otherwise encourage use of its devices as suitable for pedicular attachment, the fact that it was engaged in

promotional activities also raises material questions regarding management's credibility.

Although the panel emphasized the fact that Sofamor Danek's promotional activities were never proven to be illegal, and that Sofamor Danek apparently never faced FDA action concerning its undisputed promotional activities, this emphasis is unwarranted. (The panels, emphasis on these facts appeared in connection with its analysis of whether a duty to disclose existed with regard to Sofamor Danek's omission to disclose the facts of its promotional activities.) For that part of the SDG Investors' claim based on the Company's *affirmative* false statements (as opposed to an omission), it is irrelevant. The relevant analysis for this claim is simply whether Sofamor Danek made the false statements, and whether these statements were material to the reasonable investor. *See, e.g., Aschinger v. Columbus Showcase Co.*, 934 F.2d 1402, 1409 (6th Cir. 1991). As shown above, Sofamor Danek's statements representing that it did not in any way promote or encourage use of its devices as suitable for pedicular attachment are clearly and *demonstrably false*.[2] Due to the very real (and, in fact, as

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[2] For example, in its 1992 10-K, the Company stated that its Bone Plate and Screw Product Line is "not presently labeled **or promoted** for [pedicular attachment]," and that it "does **[not] encourage** the use of products for unapproved uses." J.A. at 285A (emphasis added). See also

far as civil lawsuits go, *realized*[3]) consequences the Company could potentially face as a result of its promotional activities (regardless of actual legality), any reasonable investor would have considered the Company's *clearly false* statements as having altered the total mix of available information. In short, Sofamor Danek's undisputed, demonstrably false material statements representing that it did not promote or encourage its Bone Plate and Screw line as suitable for pedicular attachment is sufficient, standing alone, to support a § 10(b) and Rule 10b-5 claim against the Company.

B. The Information Sofamor Danek Wrongly Omitted to Disclose Was Not Whether The Company's Promotional Activities Were Illegal, But the Fact That It Was Engaged in the Promotional Activities Themselves

Distinct from its violation of federal securities laws as a

1993 10-K, J.A. at 317 (similar representations). (As the Panel correctly noted, on the pending motion it is fully appropriate to consider the various public filings related to the Complaint and made part of the record by the defendants. See Panel Opn., p. 14 n.2.)

[3] As noted elsewhere, multi-million dollar civil lawsuits were brought against Sofamor Danek concerning its promotional activities.

result of its *affirmative false statements,* Sofamor Danek also violated federal securities laws by its *omission* to disclose each of the material facts evidencing its promoting and encouraging use of its devices as suitable for pedicular attachment. The Company's duty to disclose arose for either of two reasons. One reason is Simply due to the fact. that Sofamor Danek already had made clearly *false* statements to the contrary (discussed above). It is axiomatic that, even in situations where a company would normally not have a duty to speak, once the company undertakes to speak at all it undertakes the duty to speak *truthfully. See, e.g., First Virginia Bankshares v. Benson,* 559 F.2d 1307, 1317 (5th Cir. 1977), *cert. denied,* 435 U.S. 952 (1978). As such, to the extent that disclosure Of the facts underlying its promotional activities might. have served to ameliorate its false statements to the contrary, disclosure was mandated.

Even were Sofamor Danek's statements - representing that it did not engage in promotional activities for pedicular attachment - somehow not literally false (which, in this case, they are), however, the fact would still remain that Sofamor Danek voluntarily chose to speak on the issue. As such, Sofamor Danek *also voluntarily assumed the duty to disclose all material facts on the issue of promotion necessary to insure the statements it did make were not misleading. See id.*

In the Panel's anal,sis of the SDG Investor's "omission" claim, the Court emphasized that Sofamor Danek did not have a duty to disclose it was illegally promoting its devices

for which it faced possible FDA sanction because (1) even though it is undisputed that Sofamor Danek was promoting the use of its devices as suitable for pedicular attachment, whether the Company's promotional activities were actually illegal was a matter of opinion (*i.e.*, "soft" information); and (2) it appears that Sofamor Danek ultimately did not face any FDA action or sanction. Panel Opn., pp. 15-16. This analysis, however, confuses the question of whether the Company had a ***duty to disclose***, with the question of what *facts or information* should be disclosed. As noted above, a duty to disc-Lose was firmly established once the Company chose to speak at all.

In regard to what Sofamor Danek should have disclosed, it may very well be correct to hold that Sofamor Danek was not required to inform investors that, in its opinion, the promotional activities in which it was engaged constituted "illegal" conduct. This conclusion, however, which is the entire focus of the Panel Opinion, is off the mark. The SDG Investors do not assert that Sofamor Danek should necessarily have disclosed the "soft" information that it was engaged in promotional activities that were "illegal;" rather the SDG Investors claim that Sofamor Danek should have disclosed the "hard" information that it was *engaged in these promotional activities. See, e.g., In re Par Pharmaceutical, Inc. Sec. Litig.*, 733 F. Supp. 668, 677-78 (S.D.N.Y. 1990) (although the company was not required to disclose the "predicted consequences" of its bribery scheme, it was a jury question regarding whether it should have

disclosed *the facts of the scheme itself).*

Specifically, Sofamor Danek should have disclosed *hard* facts such as that:

1. It funded the so-called Spinal Science Advancement Foundation ("SSAF"), which in turn sponsored numerous programs promoting the use of Sofamor Danek's Bone Plate and Screw Product Line for pedicular fixation;
2. It funded numerous seminars and programs that encouraged - indeed, demonstrated - the use of Sofamor Danek's Bone Plate and Screw Product Line for pedicular attachment; and
3. It stationed its salespersons right inside operating rooms during surgeries in which its Bone Plate and Screw Product Line was actually used for pedicular attachment. In fact, on occasion its salespersons would *assist* in the surgeries.

When, in its Panel Opinion, the Court found Sofamor Danek had no duty to disclose, what the Court was really saying was that there was no duty to disclose the "soft" information such as *whether the promotional activities were illegal.* In so doing, the Court jumped too far ahead and collapsed the analysis. As described above, because Sofamor Danek voluntarily chose to speak, it necessarily assumed the duty to speak truthfully and completely. As a result, "duty" was clearly established. Since the duty to disclose, however, only applies to material information, the Court should have analyzed whether the Company was required to disclose the "hard" information concerning the

fact that it was engaging in the promotional activities themselves *(i.e.,* the undisclosed funding of programs, seminars and the SSAF, etc.). In other words, was this "hard" information material. As far as whether the activities were illegal or improper, if the "hard" information concerning the activities themselves had been disclosed, investors themselves could have reached their own conclusions regarding such significant issues as: whether the activities were in violation of FDA regulations; the likelihood of the Company facing FDA action or civil lawsuits; or any other potential consequence implicated by the Company's undisputed promotional activities.

The Court also placed undue emphasis on the tangential fact that Sofamor Danek never faced any FDA regulatory action. That the Company ultimately never faced such an action, however, is irrelevant. Indeed, it would be irrelevant if Sofamor Danek *had* faced FDA regulatory action (or if Sofamor Danek were notified during this appeal that the FDA was initiating an action), as it is likewise irrelevant that the Company actually *did* face substantial civil lawsuits from patients whose surgeons had utilized Sofamor Danek's devices for pedicular attachment. As the SDG Investors warned in their Brief of Appellant, relying on such after-the-fact occurrences (or non-occurrences) would be akin to the soundly rejected "fraud-by-hindsight."

Furthermore, the fact that no enforcement action was ever instituted no more proves Sofamor Danek's activities were legal than the mere institution of an action would have

proven the activities were illegal. For reasons more related to scarcity of federal funds and enforcement resources than to guilt or innocence, wrong doings often go unchallenged. More importantly, the operative issue is not whether Sofamor Danek's promotional activities were provable violations of the law, but rather whether, in light of Sofamor Danek's numerous and patently misleading statements claiming it did not encourage or promote use of its Bone Plate and Screw Product Line for pedicular attachment, investors had a right to know the undisclosed facts concerning Sofamor Danek's undisputed promotional activities (e.g., undisclosed sponsorship of seminars, programs, the SSAF, stationing salespersons in operating rooms who sometimes assisted in the surgery). In other words, would such information be significant to the reasonable investor in making trading decisions. The answer is yes; whether the activities were legal or not, the questions and issues necessarily raised by these practices mandated their disclosure. By omitting to disclose this "hard" information, Sofamor Danek's contrary statements misled investors.

V. CONCLUSION

For the foregoing reasons, the SDG Investors respectfully request. that the Court reverse the panel's opinion, find that the Complaint adequately states claims under the federal securities laws, and remand this matter to the District Court for further proceedings.

Date: August 28, 1997

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FILING AND MAILING CERTIFICATE

I hereby certify that on this 28th day of August 1997, I filed with the Clerk's office of the United States Court of Appeals for the Sixth Circuit the required twenty-five copies of this PETITION FOR REHEARING AND SUGGESTION FOR REHEARING *En Banc* and further certify that I mailed via U.S. Mail this same date from Cincinnati, Ohio one copy to opposing counsel.

The necessary filing and mailing was performed in accordance with the instructions given me by counsel in this case.

/s/ Niki Stockton
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APPENDIX F

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

COMPLAINT

Civil Case Nº.: 94-2303-TU
Filed September 2, 1994

Pages F-1 thru F-62

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

FILED
94 SEP 2

IN RE	:	
SOFAMOR DANEK GROUP	:	**Civil Action No.**
INC. SECURITIES	:	**94-2303 TU**
LITIGATION	:	
	:	
	:	
THIS DOCUMENT RELATES	:	
TO:	:	
ALL ACTIONS	:	
	:	

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Plaintiffs, by their attorneys, for their Consolidated Amended Class Action Complaint, allege upon personal knowledge as to themselves and their own acts and as to all other matters upon information and belief, based upon *inter alia,* the investigation made by their attorneys, which included, but is not limited to, a review of the public filings

of Sofamor Danek Group, Inc. ("SDG" or "the Company"), and numerous news articles concerning the Company, as follows:

I. JURISDICTION AND VENUE

1. Jurisdiction and venue of this Court are founded on Section 27 of the Securities and Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78aa, Sections 1331 and 1337 of Title 28, 28 U.S.C. § 1331, 1337, and principles of supplemental jurisdiction, 28 U.S.C. § 1367.

2. The claims herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the Securities and Exchange Commission (the "SEC").

3. Venue is proper in this District as the acts and conduct charged herein, including the filing and dissemination of false and misleading reports and the issuance of materially false and misleading information to the investing public, occurred in this District.

4. In connection with the acts, conduct, combination and course of conduct alleged in this Complaint, the defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mails and interstate telephone communications, and the facilities of the national securities markets.

II. THE PARTIES

5. Plaintiff Bruce G. Murphy purchased 100 shares of SDG common stock on August 20, 1993 at $33¼ per share.

6. Plaintiff Randy Owen purchased 345 shares of SDG common stock on November 4, 1993 at $31.50 per share.

7. Plaintiff Mary Kennedy purchased 200 shares of SDG common stock on February 17, 1993 at $36 per share.

8. Plaintiff Lynda Kramer purchased 325 shares of SDG common stock on July 1, 1993 at $36 per share and 300 shares on March 8, 1994 at $28 per share.

9. Plaintiff Mike Roberts purchased 500 shares of SDG common stock on April 15, 1994 at $20-3/8 per share.

10. Defendant SDG has its principal executive offices at 3092 Directors Row, Memphis, Tennessee.

11. The Company's stock was traded on the NASDAQ National Market System until November 22, 1993. Since that time, it has traded on the New York Stock Exchange.

12. Defendant SDG is the world's largest developer, manufacturer and marketer of internal fixation devices for spinal fusion. The Company sells approximately 65% of the internal fixation devices used in the domestic spinal fusion market and has about 20% of the international market. The Company was created through the merger of Danek Group,

Inc. ("Danek Group") and Sofamor, S.A. ("Sofamor") which became effective in June, 1993. Sofamor, was primary engaged in the development, manufacturing, and marketing of spinal implant devices, which were used in the surgical treatment of spinal degenerative diseases, deformities, trauma-induced disorders and resection of tumors.

13. Defendant E. Ron Pickard ("Pickard") was the President, Chief Executive Officer and a Director of Danek Group and SDG. Pickard signed Danek Groups form 10-Q for the quarterly period ended March 31, 1993, Danek Group's Form 10-K for the year ended December 31, 1992, SDG's Form 10-Qs for the periods ended June 30, 1993 and September 30, 1993, and SDG's Form 10-K for the year ended December 31, 1993. On the following dates, defendant Pickard sold a total of 24,342 shares of SDG common stock and reaped proceeds of over $800,000 while in possession of material adverse non-public information while under a duty to disclose such information or abstain from trading:

Date of Sale	No. of Shares	Sale Price	Gross Receipt (exclusive of commissions)
2/18/94	20,989	$34.01	$713,835.89
2/23/94	3,353	$33.00	$110,649.00
TOTAL	24,342		$824,484.89

14. Defendant Laurence Y. Fairey ("Fairey") was

Executive Vice President and Principal Financial Officer of Danek Group and SDG. Fairey signed Danek Group's Form 10-K for the quarterly period ended March 31, 1993, Danek Groups Form 10-K for the year ended December 31, 1992, SDG's Form 10-Qs for the periods ended June 30, 1993 and September 30, 1993, and SDG's Form 10-K for the year ended December 31, 1993. On the following dates, defendant Fairey sold a total of 6,000 shares of SDG common stock and reaped proceeds of over $190,000 while in possession of material adverse non-public information while under a duty to disclose such information or abstain from trading:

Date of Sale	No. of Shares	Sale Price	Gross Receipt (exclusive of commissions)
11/01/93	4,000	$32.94	$131,760.00
11/17/93	2,000	$29.94	$ 59,880.00
TOTAL	6,000		$191,640.00

15. Defendant Leander D. Beard ("Beard") served as Chairman of the Board of Danek Group and SDG during the Class Period until he retired from that position on May 23, 1994. Defendant Beard continued as a director of SDG after retiring as Chairman. On the following dates, defendant Beard sold a total of 115,000 shares of SDG common stock and reaped proceeds of over $3.7 million while in possession of material adverse non-public information while under a duty

to disclose such information or abstain from trading:

Date of Sale	No. of Shares	Sale Price	Gross Receipt (exclusive of commissions)
11/01/93	15,000	$33.13	$ 496,950.00
11/08/93	70,000	$32.50	$2,275,000.00
11/08/93	30,000	$32.79	$ 983,700.00
TOTAL	115,000		$3,755,650.00

16. Defendant George F. Rapp ("Rapp") served on the Board of Directors of Danek Group and SDG during the Class Period. On the following dates, defendant Rapp sold a total of 193,030 shares of SDG common stock and reaped proceeds of over $6.3 million while in possession of material adverse non-public information while under a duty to disclose such information or abstain from trading:

Date of Sale	No. of Shares	Sale Price	Gross Receipt (exclusive of commissions)
11/03/93	20,000	$33.50	$ 650,000.00
11/10/93	18,000	$31.90	$ 574,200.00
11/18/93	12,000	$30.38	$ 364,560.00
11/19/93	11,400	$30.13	$ 343,482.00
2/22/94	78,240	$33.97	$2,657,812.80
2/22/94	36,390	$33.97	$1,236,168.30
2/23/94	17,000	$33.30	$ 566,100.00
TOTAL	193,030		$6,392,323.10

17. Defendant Miles D. Igo ("Igo") served as a Director of SDG during the Class Period. Defendant Igo signed Danek Group's Form 10-K for the year ended December 31, 1992. On the following dates, defendant Igo sold a total of 37,699 shares of SDG common stock and reaped proceeds of over $1.2 million while in possession of material adverse non-public information while under a duty to disclose such information or abstain from trading:

Date of Sale	No. of Shares	Sale Price	Gross Receipt (exclusive of commissions)
11/02/93	2,500	$32.50	$ 81,250.00
11/26/93	2,500	$34.25	$ 85,625.00
12/06/93	5,000	$35.00	$ 175,000.00
12/20/93	3,500	$31.13	$ 108,955.00
1/18/94	4,199	$34.00	$ 142,766.00
1/19/94	4,000	$34.25	$ 137,000.00
1/19/94	6,000	$34.38	$ 206,000.00
1/28/94	10,000	$36.00	$ 360,000.00
TOTAL	37,699		$1,296,596.00

18. Defendant Alan J. Olsen ("Olsen") served as a Director of SDG during the Class Period and was Executive Vice President of Danek Group and the President of Danek Medical, Inc. prior to the merger. Defendant Olsen signed Danek Group's Form 10-K for the year ended December 31, 1992. On the following dates, defendant Olsen sold a total of

72,539 shares of SDG common stock and reaped proceeds of over $2.3 million while in possession of material adverse non-public information while under a duty to disclose such information or abstain from trading:

Date of Sale	No. of Shares	Sale Price	Gross Receipt (exclusive of commissions)
11/03/93	10,000	$31.75	$ 317,500.00
11/04/93	40,000	$31.50	$1,260.000.00
2/18/94	22,539	$34.01	$ 766,551.39
TOTAL	72,539		$2,344,051.30

19. Defendant Yves Paul Cotrel ("Y. Cotrel") served as a Director of SDG during the Class Period and was the former Chairman of the supervisory Board of SDG's wholly-owned French subsidiary, Sofamor S.N.C. On the following dates, defendant Y. Cotrel sold a total of 255,354 shares of SDG common stock and reaped proceeds of over $7.7 million while in possession of material adverse non-public information while under a duty to disclose such information or abstain from trading:

Date of Sale	No. of Shares	Sale Price	Gross Receipt (exclusive of commissions)
11/15/93		$31.00	$ 169,973.00
11/28/93	5,483	$30.08	$6,916,625.20
2/18/94	229,941	$34.01	$ 584,495.86
2/23/94	17,186	$33.00	$ 90,552.00
	2,744		
TOTAL			$7,761,646.00
	255,354		

20. Defendant Phillipe Cotrel ("P. Cotrel") served as a Director of SDG during the Class Period and was the former Chief Executive Officer and Chairman of the Directorate, Sofamor, S.N.C. On the following dates, defendant P. Cotrel sold a total of 24,079 shares of SDG common stock and reaped proceeds of over $724,000 while in possession of material adverse non-public information while under a duty to disclose such information or abstain from trading:

Date of Sale	No. of Shares	Sale Price	Gross Receipt (exclusive of commissions)
11/15/93	560	$31.00	$ 17,360.00
11/18/93	23,519	$30.08	$ 707,451.52
TOTAL	24,079		$ 724,811.52

21. Each of the defendants is liable as a direct

participant in the wrongs complained of herein. Additionally, because of their positions of control and authority as officers and/or directors of SDG and/or its predecessor Danek Group, the individual defendants were able to and did control the contents of the various reports, press releases and the statements of SDG and were "controlling persons" of SDG and/or Danek Group within the meaning of Section 20 of the Exchange Act. As officers and/or directors of a publicly held company, the defendants had a duty to promptly disseminate and/or ensure the prompt dissemination of accurate and truthful information with respect to SDG's operations, prospects and financial status and to promptly correct any public statements issued by SDG or from any source which had become false or misleading.

22. The liability of each defendant arises from the fact that each engaged in either all or part of the unlawful acts, plans, schemes, transactions, artifices to defraud and other violations charged herein. In addition, there may be other persons, presently unknown to plaintiffs, who have conspired with the defendants named herein and committed acts in furtherance of the wrongdoing alleged herein.

II. PLAINTIFFS' CLASS ALLEGATIONS

23. The named plaintiffs bring this action as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules

of Civil Procedure ("FRPC") on behalf of a class (the "Class") consisting of all persons who purchased the common stock of SDG (or its predecessor, Danek Group) during the period February 8, 1993 through and including April 21, 1994 (the "Class Period"). Excluded from the Class are SDG and its subsidiaries and affiliates, the individual defendants herein, other officers and directors of SDG and Danek Group during the Class Period, members of the immediate family of each defendant, and the legal representatives, heirs, successor or assigns of any of the individual defendants.

24. Members of the Class are so numerous and geographically dispersed that joinder of all class members is impracticable. As of March 31, 1994, there were 24,398,838 shares of SDG common stock outstanding.

25. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

26. Plaintiffs' claims are typical of the claims of the members of the Class as plaintiffs and all members of the Class sustained damages arising out of defendants' wrongful conduct in violation of federal and state laws complained of herein.

27. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all Class members is

impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for the Class members to individually redress the wrongs done to them.

28. There are questions of law and fact common to this Class which predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to this Class are:

(a) whether the federal securities laws and state laws were violated by defendants' act as alleged herein;

(b) whether defendants participated in and pursued the common course of conduct complained of herein;

(c) whether documents and statements, including those disseminated to the investing public during the Class Period, omitted and/or misrepresented material facts about the business affairs, financial condition and future prospects of SDG;

(d) whether the defendants acted willfully, recklessly or negligently in omitting to state and/or misrepresent material facts;

(e) whether the market price of SDG common stock during the Class Period was artificially inflated due to the non-disclosure and/or misrepresentations complained of herein; and

(f) whether the members of the Class have

sustained damages, and, if so, what is the proper measure of damages.

29. Plaintiffs know of no difficulty which will be encountered in the management o this litigation which would preclude its maintenance as a class action.

IV. BACKGROUND

30. SDG develops, manufactures and markets spinal implant devices used in the surgical treatment of spinal degenerative diseases and deformities. Its products also increase stability during the healing of spinal trauma. The Company's principal products include the TSRH (Texas Scottish Rite Hospital) Spinal System Product Line, the Cotrel-Dubousset Spinal Instrumentation System (the "CD System"), the Compact Cotrel-Dubousset System (the "CCD System") and the Danek Bone Plate and Screw Product Line.

31. The TSRH group of products is a specialized system of hooks, rods and bolts used by surgeons primarily to treat patients afflicted with scoliosis and severe deformities under Section 510(k) approval from the FDA. This section enables manufacturers to avoid expensive and lengthy human clinical trials and more complex submissions (typical of full pre-market approval) required to prove safety and efficacy. Sales of all products of the TSRH Spinal Product Line accounted for 53% of the Company's consolidated sales in

1993.

32. The CD System, which was a Sofamor product, includes spinal rods, hooks, and transverse traction devices which lock implants together and is principally used to treat deformities and fractures of the long spine in the thoracic and lumbar regions. This system is market as a spinal device pursuant to Section 510(k). The CD system accounted for 18% of the Company's consolidated sales in 1993.

33. The CCD System, which was also a Sofamor product, was designed principally for the treatment of degenerative spinal conditions of the lumbar and sacral spine and incorporates the same type of components found in the CD System. This system is marketed pursuant to Section 510(k). The CCD System accounted for 16% of the Company's consolidated sales in 1993.

34. The Danek Bone Plate and Screw Product Line consists of metal plates and screws that are attached to bones to achieve fixation during the healing process. Danek markets these products pursuant to a Section 510(k) clearance, which does not encompass all spinal uses. Danek can market its bone plates and screws for some spinal uses (anterior placement), but it cannot market these plates and screws for all uses (i.e., posterior placement).

35. The Company filed an application for an investigative device exemption ("IDE") with the FDA on June 27, 1986 to perform clinical research studies with the Danek

Bone Plate and Screw for pedicular spinal fixation. The Danek Bone Plate and Screw Product Line accounted for 1% of the Company's consolidated sales in 1993. However, screws for pedicle use were also marketed under SDG's other product lines, including the TSRH Spinal Product Lines.

36. In December, 1992, Danek received approval from the FDA to market the Dyna-Lok system in the U.S. for thoracic and lumbar spine sues. Dyna-Lok provides rigid or semirigid fixation within a single system.

37. On March 28, 1993, Danek Group entered into a stock exchange agreement with the shareholders of Sofamor, a French privately-held company. The Agreement provided for the exchange of all of the Sofamor capital stock for common stock of Danek Group and a cash payment to one dissenting holder of Sofamor, who owned approximately 2.7% of Sofamor capital stock.

38. At Danek Group's June 21, 1993 annual shareholder meeting, the combination of Danek Group with Sofamor was approved. Under the Agreement, Sofamor became a wholly-owned subsidiary of Danek Group, which was renamed Sofamor Danek Group. The common stock of Danek Group continued to trade, but under the SDG name.

V. DEFENDANTS' PUBLIC STATEMENTS DURING THE CLASS PERIOD

39. In a February 8, 1993 press release, Danek Group

reported record sales and net income for the fourth quarter and year ended December 31, 1992. Net sales for the fourth quarter increased 82% to $22.7 million compared with sales of $12.5 million in the fourth quarter of 1991. Net income increased 88% to $4.2 million, or $.24 per share, compared with $2.2 million, or $.13 per share in the fourth quarter of 1991. For the year ended December 31, 1992, net sales increased 82% to $75.5 million compared with $41.4 million for 1991. Net income for 1992 increased 98% to $13.1 million, or $.74 per share, compared with $6.6 million, or $.40 per share for 1991. Defendant Pickard stated in the press release as follows:

> Danek recorded its seventh consecutive quarterly increase in sales and net income since the initial public offering in 1991. Our excellent results are due to the continued growth in the spinal market, expanded sales of our proprietary TSRH(R) line of spinal products and to expanded international sales.
>
> * * *
>
> Danek recently received FDA acceptance to market its proprietary Dyna-Lok System for anterolateral use in the thoracic and lumbar spine. The Dyna-Lok system provides semi-rigid or rigid fixation within a single system. In addition, the FDA accepted the Paragon

System (formerly Chiba System) for marketing in the U.S. by Danek. The Paragon System utilizes a patented, tapered locking sleeve to interconnect the components. We believe the addition of these product lines will further enhance our competitive position in the spinal market.

40. On March 29, 1993, Danek Group announced the signing of definitive agreements for the combination of Danek Group with Sofamor, S.A. Defendant Pickard touted the positive effects of the combination:

> The proposed combination with Sofamor will significantly increase our international presence.
>
> * * *
>
> Sofamor has an outstanding record of growth and profitability. They have an experienced management team and a well trained organization that is totally focused on spinal products. We believe the combination of experience and talent with in the two companies will accelerate our collective product development. In addition, Sofamor provides the international infrastructure to launch new products abroad without U.S. regulatory delays.

41. Wall Street reacted positively to news of the merger, with Danek Group's stock price jumping $4 1/8 on March 29, 1993. Morgan Keegan analyst Joseph Millsap was quoted as stating that Danek's 1993 earnings could be as high as $1.20 per share following the merger. His then current 1993 estimate was $1.12 per share. Millsap also stated that the merger would make SDG "the strongest implant manufacturer on a global basis."

42. Similarly, Wessels Arnold & Henderson analyst Samuel Murphy estimated that the deal would add six cents a share to Danek's 1993 earnings, which he now estimated to be $1.11 per share — up from 74 cents a share in 1992.

43. Danek Group filed its annual report on Form 10-K for the year ended December 31, 1992 with the SEC on or about March 31, 1993. In the Form 10-K, Danek Group attributed its net sales growth of 82.2% over 1991 to increased sales volume in spinal implant products. The Company attributed the increase in sales volume primarily to a combination of the growth in the number of spinal implant procedures as well as increased use of the Company's products in those procedures. The Company's gross profits were also reported as increasing as a percentage of sales from 77.8% in 1991 to 82.6% in 1992. These improvements were primarily attributed to favorable shifts in sales mix, leveraging of fixed costs at the Company's manufacturing facility, and the effects of a price increase implemented May

1, 1991 on selected spinal systems.

44. In the Form 10-K, Danek Group reported as assets $2.07 million in "loaner set inventories" as of December 31, 1992 — an increase from $550,000 as of December 31, 1991. Loaner set inventories were described as:

> . . . certain inventory items on loan or available to be loaned to customers. The inventory items used by the customer in surgery are recorded as sales when used with the remaining inventory in the set being returned to the Company. The Company maintains an inventory reserve for its estimate of goods damaged in the loaner program. This estimate is based upon historical data maintained by the Company.

45. On or about April 19, 1993, Danek Group reported record sales and net income for the first quarter ended March 31, 1993. Net sales for the first quarter improved 52% to $22.6 million compared with net sales of $14.9 million in the first quarter of 1992. Net income increased 88% to $4.2 million, or $.24 per share, compared with $2.3 million, or $.13 per share in first quarter of 1992. Income from operations increased by 91% to $6.6 million compared with $3.4 million in first quarter of 1992. This improvement, claimed defendant Pickard, was due to Danek's higher sales base, improved manufacturing efficiencies and

the leveraging of general administrative expenses. Danek's gross margin was reported as increasing to 82.2% in the quarter.

46. On or about May 16, 1993, Danek Group filed its Form 10-Q with the SEC for the first quarter of 1993 ended March 31, 1993. Defendants attributed substantially all of the Company's increase in sales revenues to increased sales volume in spinal implant products. The Company's gross profits increased as a percentage of sales from 81.5% in the first quarter of 1992 to 82.2% in the first quarter of 1993. These improvements, defendants claimed, were primarily due to favorable shifts in sales mis and the leveraging of fixed costs at the Company's manufacturing facility. On its balance sheet, Danek Group listed loaner set inventories at $2,285,000 as of March 31, 1993, a slight increase over the $2,070,000 as of December 31, 1992.

47. in a May 21, 1993 Reuters article, defendant Pickard was reported as stating that he was "very comfortable" with analyst' estimates that Danek Group would earn $.25-.27 per share in the second quarter of 1993, based upon continued strong growth in its spinal implant products business. Pickard also stated that he was comfortable with projections that Danek's overall sales would grow by 50-55 percent in 1993 and would grow at a compounded average annual rate of 30 percent in the next 3-5 years.

48. In a July 26, 1993 press release, defendant

Pickard reported record sales and pro forma net income for SDG for its second quarter of 1993 ended June 30, 1993. SDG's sales rose 34% to $40.3 million as a result of "increased demand for the company's TSRH and CCD product lines." Pro forma net income for the second quarter of 1993 increased 42% to $6.9 million or $.28 per share compared with net income of $4.9 million, or $.20 per share in the second quarter of 1992. The pro forma results presented comparable operations of the Company for each period and did not include merger costs, discontinued royalties and certain Sofamor businesses that were not included in the merged operations of SDG.

49. In its Form 10-Q for the period ended June 30, 1993, filed with the SEC on or about August 15, 1993, SDG reported that 96% of the 33.5% increase in net sales for the three months ended June 30, 1993 as compared to the three months ended June 30, 1992 were attributable to increases in volume. Net sales increases were described as being primarily a result on increased demand for the Company's TSRH Spinal System and CD System. Gross profits were reported as increasing as a percentage of sales from 76.1% and 76.6% in the second quarter and first half of 1992, respectively, to 77.3% and 77.7% in the second quarter and first half of 1993, respectfully. The improvements were described as primarily due to favorable shifts in sales mix, increased volume, and leveraging of fixed costs at the

company's manufacturing facilities. Loaner set inventories were reported as increasing from $4,117,000 as of December 31, 1992 (for Danek Group and Sofamor) to $5,619,000 as of June 30, 1993.

50. On or about October 20, 1993, defendant Pickard reported record sales and net income for the third quarter and nine months ended September 30, 1993. The Company also reported that it had filed a listing application with the New York Stock Exchange and anticipated trading to begin in November, 1993. Defendant Pickard stated:

> Sofamor Danek's sales momentum continued in the third quarter as a result of the growth of spinal surgery in both domestic and international markets. Domestic sales rose 35.6% in the most recent quarter and international sales were up 19.5% compared with the third quarter of last year.
>
> Net sales for the third quarter advanced 31.3% to $42.6 million compared with sales of $32.4 million in the same quarter of 1992. Domestic sales totaled $32.4 million and accounted for 76% of consolidated revenues and international sales were $10.2 million, or 24% of total revenues in the latest quarter.
>
> Pro forma operating income for the third quarter rose 28.1% to $12.7 million and

represented 29.9% of sales. Pro forma net income increased 25% to $7.9 million, or $0.32 per share, compared with $6.4 million, or $0.26 per share, in the third quarter of 1992.

51. Continued Pickard:

We have made significant strides in integrating our distribution networks. The merger has broadened the range of product offerings for our sales force world wide. We have attended several medical meetings with conventions since the merger and we are pleased with the positive response and feedback from spinal surgeons regarding our expanded product lines.

52. SDG's Form 10-Q for the third quarter of 1993 ended September 30, 1993 noted that approximately 95% of the increase in sales for the third quarter of 1993 compared to the same period in 1992 was due to increases in volume. The Company's gross profits decreased as a percentage of sales from 80.2% and 78.0% in the third quarter and first nine months of 1992, respectively, to 78.3% and 77.9% in the third quarter and first nine months of 1993, respectively. The decrease in gross profit margins was described as being mixed primarily due to unfavorable shifts in sales mix which was affected by the increase in participation in certain of the

Company's promotional programs. This unfavorable shift in sales mix, however, was "somewhat offset" by the favorable result of increased volume and leveraging of fixed costs at the Company's manufacturing facilities. Loaner set inventories were reported as increasing from $4,117.000 as of December 31, 1992 to $6,357,000 as of September 30, 1993.

53. On or about November 22, 1993, SDG's shares began trading on the New York Stock Exchange.

54. On January 12, 1994, defendant Pickard was quoted in a Reuters' article as stating that he was comfortable with analysts' earnings estimates for 1993 which ranged from $1.17 to $1.20 per share. Moreover, he told Reuters that he was also "pretty comfortable" with analysts' projections of earnings growth in 1994 of 25 to 30 percent.

55. On or about January 14, 1994, SDG announced that five patients and their spouses had filed a lawsuit against it alleging that surgical screws had been implanted illegally in their spines, that the screws were not approved by the FDA for use in certain spinal surgeries, yet the Company continued to promote the devices to customers and surgeons. This lawsuit came on the heels of a December, 1993 "20/20" television news report on the dangers of spinal fusion using pedicle screws. SDG was not named in that report.

56. On or about February 14, 1994, defendant Pickard reported in a press release that SDG achieved record sales and net income for the fourth quarter and year ended December

31, 1993. Pickard stated that SDG's sales rose 32% to $44.4 million in the fourth quarter of 1993 and pro forma net income increased 52% to $9 million or $.36 per share compared with net income of $5.9 million, or $.24 per share in the same quarter in 1992.

57. For the year ended December 31, 1993, SDG's sales had increased 34% to $161.8 million compared with 1992 sales of $121 million in 1992. Pro forma net income rose 45% to $29.9 million, or $1.21 per share, compared with 1992 pro forma net income of $20.6 million, or $.84 per share. Defendant Pickard stated in the February 14, 1994, press release that:

> Our earnings gained momentum in the fourth quarter as a result of higher system sales of our TSRH(R) and CCD(TM) product lines, the contribution of new products released since mid-year and continued leveraging of operating costs.
>
> * * *
>
> Our proprietary TSRH and CCD product lines continued as our sales leaders in the fourth quarter. We made significant enhancements to the TSRH product line during 1993 which expanded its potential applications in spinal surgery. The demand for the CCD product line has continued to grow since its launch in

August.

58. On or about March 2, 1994, SDG announced that James Gallogly would join the Company in a newly-created position of Chief Operating Officer and would also take on the role of Company President. Defendant Pickard, who had been serving as President and CEO would replace defendant Beard as Chairman, who was retiring.

59. In late February and March 1994, analysts covering SDG began to slightly lower SDG earnings and revenue estimates. For example, on February 28, 1994, Smith Barney lowered its long-term earnings per share growth rate projection to 20% from 25% and its 1994 price target to $30-32, from $38 per share. Smith Barney claimed that the downgrade was related to SDG's January sales falling below the Company's budget, ". . . presumably due to a postponement in elective spinal implant surgeries due to the bad weather in the Midwest and East and the Los Angeles earthquake."

60. Similarly, in a March 1, 1994 Robert W. Baird analyst report, projections for 1994 domestic SDG sales were lowered to $124 million from an initial forecast of $134 million. Baird, however, still projected an increase in domestic sales of 25% for 1994, with total 1994 revenues forecast at $204 million as compared to an original estimate of $215 million. Baird called the sales downturn a "temporary slowness" and blamed it on a "difficult winter"

and the "20/20" news show which portrayed the spinal fusion market as a dangerous area for patients.

61. In a March 2, 1994 Morgan Keegan analyst report, first quarter 1994 revenue estimates for SDG were reduced from $41.4 million to $40 million, although 1994 revenue estimates remained at $198.5 million. Morgan Keegan also blamed the revenue softness on the harsh winter and "spillover from the 20/20 news segment in December."

62. In SDG's 1993 Annual Report on Form 10-K, filed with the SEC on or about March 31, 1994, SDG attributed 97% of the increase in sales from 1992 to 1993 to an increase in "sales volume." The total net sales increase was described as being primarily a result of increased demand for the Company's TSRH and CCD product lines and new demand for eight spinal systems introduced in 1993.

63. In an April 21, 1994 press release, SDG reported results of operations for its first quarter ended March 31, 1994. The Company reported that net income rose $34.1% to $8 million or $.32 per share in the first quarter of 1994 compared to the prior year, and that the Company's earnings growth benefitted from higher sales of its proprietary product lines, the contribution of product lines introduced during 1993 and the continued leveraging of operating costs. First quarter sales increased 13% to $39.1 million compared with sales of $34.6 million in the first quarter of 1993. The Company's first quarter sales growth of 13% fell below most analysts'

expectations and recent Company guidance. The Company, however, while announcing that the first quarter earnings were "on target," stated, through defendant Pickard, that its slower domestic sales were the result of a combination of factors including caution relating to the regulatory and legal environment surrounding certain aspects of spinal surgery and weather-related postponements of spinal surgery. SDG further reported in the press release that its Board had authorized the Company to engage in an open market stock repurchase program.

64. The Company also held a conference call with analysts on April 21, 1994 to inform them of the first quarter results and to discuss current and future business conditions. The Company announced, in the conference call, that it was recently notified by its largest U.S. distributor (Stuart-Medical/National Medical Specialty, Inc.), that the distributor would not meet its second quarter 1994 purchase commitment. During the conference call, the Company also admitted that surgeons' fears of litigation relating to the off-label use of spinal screws in the pedicle was most likely negatively impacting spinal implant sales.

65. The market reacted negatively to defendants' unanticipated and belated disclosures. On April 21, 1994, the common stock of SDG plunged 3 3/4 points on active trading of 685,600 shares, primarily due to the statements made by the Company that day. The stock continued to plummet on

April 22, 1994 and dropped another 3 1/8 points to $12 3/4 per share on volume of 1.6 million shares.

VI. DEFENDANTS' PUBLIC STATEMENTS SUBSEQUENT TO THE CLASS PERIOD

66. After the close of the Class Period, defendants made further disclosures relating to the previously withheld information.

67. In its Form 10-Q for the quarter ended March 31, 1994, filed with the SEC on or about May 15, 1994, SDG stated that slower U.S. growth rate in sales was due to:

> . . . a combination of factors, including weather-related postponements in elective spinal surgery and caution related to the regulatory and legal environment surrounding certain aspects of spinal surgery.

68. Defendants also further described the financial impact wich the Stuart/National Medical purchase commitment shortfall might have on SDG. In that regard, SDG stated in the same Form 10-Q:

> The Company has been notified by the U.S. distributor of Sofamor products that it will not meet its contractual purchase commitments during the second quarter of 1994. It is impossible to predict the extent of the

shortfall. Because of the notification mentioned above and the continuing regulatory and legal environment surrounding certain aspects of spinal surgery, it is expected that sales trends will continue to be below growth rates experienced in prior years.

69. On June 23, 1994, SDG announced in a press release that SDG's wholly-owned subsidiary, Sofamor S.N.C. had agreed, as of June 30, 1994, to terminate its distribution agreement with National Medical Specialty, Inc. ("NMS"). The release stated that NMS, which had purchased the division of Stuart Medical which distributed Sofamor products in the U.S., would be paid $25.5 million for the termination, $13.75 million of which was for the acquisition by SDG of inventory and related assets, and $1 million for an agreement not to compete. SDG announced that $10 million of the $25.5 million paid to NMS would be recorded as a material one-time charge to earnings during the second and third quarters of 1994.

70. On or about July 25, 1994, SDG announced its financial results for second quarter 1994 ending June 30, 1994. Net sales totaled $38.1 million for the second quarter — down from $40.3 million in the same quarter of 1993, with U.S. sales down 13.9%. SDG blamed the decline in U.S. sales on reduced sales by NMS as well as "the uncertainty related to the regulatory and legal environment surrounding

aspects of spinal surgery in the U.S.".

VII. THE FALSE AND MISLEADING NATURE OF THE PUBLIC STATEMENTS

71. The public statements made by defendants during the Class Period as described above were deceptive and materially false and misleading when made. These statements and reports created the impression that SDG's tremendous growth in revenues and earnings was due to an increase of legitimate unit sales of SDG's products. Defendants were aware this was not the case.

72. Defendants were aware during the Class Period that much of SDG's sales success had been due to SDG's illicit promotion of its products for use in the pedicle area of the spine. Defendants were also aware that a material percentage of their reported earnings during the Class Period were the result of its improper price gouging the SDG's "loaner sets." Moreover, defendants were aware prior to April 21, 1994, that Stuart-Medical was experiencing significant sales shortfalls of the Sofamor products and that Stuart would not meet its second quarter 1994 purchase commitment.

73. Defendants' intentional failure to disclose these facts during the Class Period (*and defendant's corresponding material misstatements relating to these facts) had its desired effect of causing SDG common stock to be traded at artificially inflated prices during the Class Period. The

Individual Defendants reaped proceeds of $24 million trading at inflated prices of $30-35 per share. When the market learned of the true state of affairs concerning SDG on April 21, 1994, the price of SDG common stock fell to under $13 per share.

A. The Market Was Unaware of Improper Promotion of SDG Products for Pedicular Use and the Material Impact of Such Promotion on the Company's Financial Position

74. Prior to entering commercial distribution, all medical devices must undergo FDA review, either pursuant to pre-market notification ("Section 510(k)") or a pre-market approval application ("PMA") filed by the manufacturer of a device. A Section 510(k) notification is a document which demonstrates that the device in question is "substantially equivalent" to a product on the U.S. market prior to May 1976. A PMA must show on the basis of clinical studies, that the device is safe and effective; thus, it is a much more complex submission that typically includes a two-year follow-up of a controlled human clinical study.

75. All of the SDG's products are devices which were cleared only pursuant to Section 510(k) notification. Federal law provides that manufacturers can label and promote medical devices only for indications that have been allowed by the FDA. The Company's Section 510(k) clearances do

not provide for use of any product for interpedicular segmental fixation — use of screws in the pedicle, a bony support structure of the spine.

76. In fact, in the FDA's November 6, 1990 notification to SDG that the TSRH Spinal System, TSRH Sacral L-Connector and Rush Bone Screw had been approved as Section 510(k) devices, SDG was warned that:

> 1. You may not label or in any way promote this device system for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column.
>
> 2. All labeling for this device system, including package label and labeling included within the package, must prominently state that the screws of this device are intended for sacral/iliac attachment only and include the statement: "WARNING — THIS DEVICE IS NOT INTENDED FOR PEDICULAR SCREW APPLICATION."

77. The FDA determined that pedicle screw fixation of the spine is a "new" use for the Company's devices. Thus, in order for the Company to be able to market and promote its screws for pedicle fixation, the Company would have to obtain pre-market approval, something it has never received.

78. despite these restrictions, SDG has promoted its systems for pedicle fixation, in direct contravention of FDA

guidelines. SDG's promotion of the devices for pedicle fixation has taken many forms, the most obvious being promotion of the pedicle screws directly by SDG's sales representatives. It is not uncommon, for example, for SDG sales representatives to actually be present next to (and assisting) the surgeon, during the implantation of the Danek screws for pedicle use.

79. Far more insidious, however, was SDG's promotion of the devices to surgeons through SDG's surreptitious sponsorship of organizations and seminars where pedicle fixation of its products was blatantly promoted.

80. SDG's recruiting and commercial activities for pedicle fixation devices occurred at, *inter alia,* the "Pedicle Fixation of the Lumbar Spine and Other Advances Techniques" meeting held at the Disney Contemporary Resort and Convention Center in Orlando, Florida, on May 13-15, 1993, and a program entitled, "Treatment of Surgical Spine Disease" held on April 14-17, 1993 at the Ritz-Carlton Hotel in St. Louis, Missouri. These programs provided information and "hands-on" training in the use of SDG's products for pedicle screw fixation.

81. The FDA however, made it abundantly clear that SDG's promotional activities were unlawful.

82. On August 11, 1993, a warning letter was issued from Ronald Johnson, Director of the Office of Compliance for the Center For Devices and Radiological Health of the

FDA concerning these programs. The letter "reminded" SDG that the FDA had not approved SDG's systems for use for pedicle fixation of the lumbar spine and that sponsorship by SDG of programs which promoted pedicular fixation was prohibited:

> The program "Pedicle Fixation of the Lumbar Spine. . ." provided information and "hands-on" training in the use of your TSRH Spinal Fixation System, and your Dyna-Lok Fixation System for pedicle screw fixation. The program brochure shows a number of sessions at which information on the use of your device and a number of sessions at which "hands-on" training in the use of your device for pedicle screw fixation were presented. From information in the brochure, it seems your firm provided informational slides and the devices used during the "hands-on" training which were provided by your firm.
>
> FDA has determined that pedicle screw fixation of the spine is a new use for these devices raising their classification from Class II to Class III, thereby requiring pre-market approval ("PMA") prior to distribution under the provisions of section 515 of the Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C.

360(e). Neither of your fixation systems have an approved PMA for this use, and no approved Investigational Device Exemption ("IDEA") exists for the Dyna-Lok Fixation System. While the TSRH Fixation System has an approved IDEA to study pedicle screw fixation, this does not permit the promotion and marketing of the devices for this use.

From the title of the program, and the topics being discussed therein, Danek had every reason to be aware of the focus of these programs on the unapproved use, pedicle screw fixation of the spine. Supporting such programs and providing devices for the purpose of hands-on training in the use of devices for this unapproved use constitutes promotion of devices for such use.

Promotion of your devices for this unapproved use adulterates them under Section 501(f)(1)(B) of the Act, 21 USC 351(f)(1)(b). Further such promotion misbrands your devices under Section 502(a) and 501(f)(1) of the Act, 21 USC 352(a) and 352(f)(1).

The introducing or delivery for introduction into interstate commerce of devices which are adulterated or misbranded is a violation of

Section 301(a) of the Act, 21 USC 331(a). Causing a device in interstate commerce to become adulterated or misbranded is a violation of Section 301(b) of the Act, 21 USC 331(b).

FDA requests that, the Danek Group, cancel all labeling and promotional material and advertisements, which claims or represents the use of these devices for pedicle screw fixation of the spinal vertebrae immediately. Distribution of such promotional material and support for such programs may result in regulatory action by the agency, including seizure, injunction or civil penalties. Further, the FDA requests that Danek cease sponsoring promotional programs which detail the use of your devices for this unapproved use, and that Danek cease supplying devices to programs which include 'hands-on' training for the use of your devices in this procedure, including programs currently scheduled. Continued distribution of such promotional material and support for such programs may result in regulatory action by the agency, including seizure, injunction or civil penalties. (emphasis added)

83. On December 16, 1993, the FDA issued a statement advising patients that pedicle screws had only been approved for use in clinical studies — not for general marketing and that their safety and effectiveness for spinal surgery had not been established by the manufacturers. The statement continued:

> On August 20, an FDA advisory committee of experts in orthopedic surgery heard and reviewed scientific data on pedicle screws. The panel said that, although these screws might be effective in treating certain types of spinal problems — such as fractures, tumors and slippage and curvature of the spine — there is little evidence that they work for other conditions. The experts said not enough is known about the short-term problems or the long-term safety and effectiveness of these devices, even for the most promising uses. They said more scientific data are needed for a full evaluation.
>
> * * *
>
> In the meantime, FDA has taken action to stop manufacturers of the screws from illegally promoting their use for spinal surgery.

84. On the heels of a December 17, 1993 "20/20" television news report on the dangers of spinal fusion using

pedicle screws, the FDA, on December 21, 1993, issued an "Update on Pedicle Screws." In that announcement, the FDA noted, *inter alia,* that although approximately 300,000 people in the U.S. have been implanted with the pedicle screws:

> . . . despite their widespread use, not enough is known about the possible short-term adverse effects of the screws when they are used in the pedicle of the spine, nor about their long-term effectiveness. Under the law, before orthopedic screws can be marketed as pedicle screws, their manufacturers must submit scientific data to FDA establishing that these devices are safe and effective for this purpose. Limited studies of pedicle screws have been ongoing for a number of years, and FDA has approved using the screws in these studies. Both the studies are still not complete, and the manufacturers have not yet accumulated enough data to show, one way or the other, whether the screws are safe and effective.
>
> * * *
>
> To encourage surgeons to use orthopedic screws in the pedicles of the spine, some manufacturers have been promoting this practice through professional advertising and training courses. <u>This type of promotion is</u>

illegal.

* * *

> On August 11, FDA warned the manufacturers to stop promoting the use of their orthopedic screws in the spine or face possible regulatory action, which could include seizure of their products, injunction or civil penalties. In addition, FDA is planning to require that manufacturers include in the labeling for the screws a statement that they are not approved for use in the spine.

(emphasis added).

85. On February 17, 1994, the FDA issued yet another update on the pedicle screws. In the report, the FDA reiterated that the use of pedicle screws was considered an "off-label" use and that:

> FDA is particularly concerned about the widespread use of pedicle screws without approval and without sufficient data to fully advise practitioners and patients about expected outcomes for various indications.

86. Defendants were aware both prior to and after the FDA warnings that they could not promote SDG's screws for pedicle fixation. Despite this, defendants engaged in a pervasive effort to promote the screws for precisely those uses. Those promotional efforts, however, have not been

confined to the two programs noted above.

87. Prior to the Class Period, SDG participated in the formation of the Spinal Science Advancement Foundation ("SSAF"). The SSAF, which like SDG is based in Memphis, identifies itself in its promotional brochures as a:

> . . . non-profit organization formed to promote activities which provide the most current information on the state-of-the-art treatment of spinal disease, to benefit both the clinician and the spine surgery patient. It is the object of the SSAF to support research, education, and spinal science advancement.

88. The SSAF sponsors numerous programs annually at which the use of pedicle screws are promoted. Since the SSAF is ostensibly unaffiliated with SDG and the promotion is ostensibly conducted by surgeons unaffiliated with SDG, the promotional activities go unregulated by the FDA.

89. SDG strongly encouraged its distributors to arrange for physicians and surgeons to attend such seminars. At SSAF seminars, plate and screw pedicle fixation was demonstrated on models of spines.

90. SSAF was originally created and funded by SDG to purposely circumvent the FDA prohibition on off-label promotion. SSAF's staff was paid/subsidized by SDG. While SDG may no longer be the sole sponsor of the SSAF, it remains the primary sponsor of the Foundation.

91. Throughout the Class Period, SDG was able to effectively, yet illegally, circumvent the FDA's prohibition of pedicle screw promotion through the operation of the SSAF and, possibly other, as yet, unnamed entities. The SSAF was used as a key marketing avenue for SDG's pedicle screws. Stated another way, the SSAF was a virtual "alter-ego" of the Company formed to illicitly market its devices for non-approved uses.

92. Defendants' statements during the Class Period were replete with both material misrepresentations and omissions. Defendants did not state that a significant part of SDG's sales were due to the illicit circumvention of FDA rules and regulations. Contrary to the impression created by defendants, SDG's sales success had been due, in substantial part, to SDG's illicit promotion of its products for implementation into the spine.

93. Yet, defendants disavowed any knowledge of wrongful promotion of pedicle screws. For example, during a telephone conference with analysts on October 20, 1993, defendant Pickard downplayed the warning letter sent to SDG by the FDA in August, 1993, claiming that the FDA simply sent the letter to everyone it thought was present at the May seminar in Orlando. He also stated that SDG would continue to comply with the FDA rules regarding medical education.

94. While SDG noted the existence of the SSAF in its 1993 Annual Report to shareholders, the Company failed to

describe SDG's true relationship with SSAF:

> The Company supports medical education to the extent permitted by the physician leadership of such programs and government regulation. Medical education has been a major catalyst in training surgeons throughout the world in the latest techniques in spinal instrumentation, resulting in broader demand for spinal implants. The Spinal Science Advancement Foundation (SSAF), a non-profit organization that sponsors lectures, workshops and training for surgeons and nurses involved in spinal surgery, and the Group International CD (G.I.C.D.), an international scientific association dedicated to advancement in spinal surgery are two organizations that provide such medical education.

95. An Orthopedic Advisory Panel formed by the FDA voted on July 22, 1994 to recommend to the FDA that the FDA reclassify rigid pedicle screw systems as Class II medical devices for two narrow indications: treatment of degenerative spondylolisthesis (slippage of a vertebra) and spinal fractures. If approved, the down-classification would enable bone screws to be labeled and marketed for use in the pedicles of the spine for specified indications. The

recommendation (which has not been acted upon by the FDA), however, was also coupled with a recommendation that the downgrade be coupled with "special controls" including strict warning labels, additional study, and more research by companies into safe and reliable materials.

96. Regardless of the FDA's eventual decision regarding the pedicle screw issue, however, it will not change the fact that, as described above, during the Class Period, defendants illicitly and improperly promoted their devices for pedicle fixation. Defendants had a duty to disclose that a significant portion of the Company's sales revenue resulted from its circumvention of FDA marketing restrictions. Thus, the market was unaware that the Company's purported success had been built, in significant part, on an unstable, uncertain foundation of illicit sales which could crumble at any time, robbing the Company of a large percentage of its future sales and potentially exposing it to stringent FDA penalties. The controversy surrounding the Company's activities led in part to its declining business in 1994, and the resulting decline in SDG's stock price.

B. The Market Was Ignorant of the Fact That a Significant Source of SDG's Earnings Were From Improper "Loaner" Sales

97. During the Class Period, SDG reiterated to the market that its growth in revenues and earnings were related

to its increase in unit sales growth. In fact, a large percentage of SDG's revenues and earnings were due directly to SDG's deceptive pricing related to sales from its "loaner" kits.

98. Under the loaner program, SDG provides a hospital with hooks, screws, rods and surgical instruments without any initial charge. Only the items used or discarded from the set are billed to the hospital. Most hospitals believed that in order to take advantage of this program (and avoid paying for expensive and possibly unnecessary SDG products outright) they would only pay a small mark-up or "premium" for the items used from the loaner small mark-up or "premium" for the items used from the loaner sets. In actuality, however, SDG was charging premiums on loaner set items which were often 100% over the regular list price.

99. SDG was aware that its loaner set premiums of 100% constituted improper price gouging. Yet SDG, both prior to and during the Class Period, made a significant number of its sales through the loaner programs. In fact, SDG's loaner set inventory, upon which defendants could earn these improper premiums, increased from $550,000 as of December 31, 1991 to $6,419,000 as of March 31, 1994 — and increase of over 1000%. By contrast, SDG's regular inventory during that time increased only 380% (from $4,892,000 to $23,628,000). This growth shows a substantial focus on loaner sets which comparatively grew from 10% of total inventory as of December 31, 1991 ($550,000/[550,000

+ 4,892,000]) to approximately 21% of total inventory as of March 31, 1994 ($6,419,000/[6,419,000 + 23,628,000]).

100. On a few occasions, hospitals discovered the price gouging on the loaner sets and confronted SDG. In those instances, SDG, tacitly acknowledging its wrongful conduct, immediately eliminated the exorbitant premiums. On at least several occasions, SDG representatives were banned from hospitals upon the discovery of these deceptive premiums. Yet SDG continued this practice through most of the Class Period.

101. Moreover, the Company misled the market into believing that the practice did not really help SDG's bottom line. For example, in a June 10, 1993 Robinson-Humphrey Company report of SDG, it was reported that although the premium pricing tended to inflate SDG's gross margins, higher servicing costs "actually cause the loaner program to have lower net margins." This conclusion was erroneous, since unbeknownst to the market, SDG routinely billed the customers for servicing costs, such as shipping fees, and sent unsterilized products. Thus, "servicing costs" did not adversely affect the margins because SDG was billing customers for those costs as well.

102. Similarly, in the October 20, 1993 conference call with analysts, defendants Pickard and Fairey downplayed any positive financial effects from loaner sales. Defendant Fairey claimed that loaner premiums from the loaner program

represented less than five percent of total sales and that the average loaner fee premium was only 27%. Pickard stated that as a percentage of consolidated sales for SDG's third quarter 1993, loaner premiums were only 4.1%. Pickard neglected to indicate, however, that the loaner premiums represented a large percentage of SDG's net income. To further deminimize SDG's reliance on the loaner set premiums, Pickard also claims that he expected loaner inventory to decrease over the next 6-12 months.

103. As the result of hospitals developing an increasing awareness of SDG's 100% loaner premiums, fewer hospitals were willing to pay those premiums. In fact, in its loaner price list beginning January 1, 1994, SDG reduced its loaner set premiums on implants to approximately 29%. Thus, due either to an increase in customers refusing to pay the exorbitant loaner set premiums and/or SDG's apparent across the board reduction in these premiums in 1994, SDG's premiums as a percentage of sales has steadily decreased, thereby negatively impacting SDG's 1994 net margins on its loaner sets and, correspondingly, on SDG's profits.

104. Notably, SDG's Form 10-K for the year ended December 31, 1992 and other public filings contained no description of the loaner set program. For the very first time, SDG's Form 10-K for the year ended December 31, 1993, filed on or about March 31, 1994, refers to "one implant purchase alternative" as being the loaner program. In the

1993 Form 10-K, defendants acknowledge (presumably due to the growing opposition to the practice) that "the customer is charged only for the components used, at a premium over published list price."

105. Thus, contrary to the impression created by defendants, SDG's positive financial results in 1993 were not related primarily to increasing unit sales of SDG's products, but were largely due to SDG's exorbitant and illegal premiums on loaner sets. Unbeknownst to the investing public, the Company's success was built, in significant part, on an exorbitant pricing premium for loaner sets that could (and did) crumble, robbing the Company of a material percentage of its revenues and earnings.

C. Defendants Failed to Timely Disclose That Stuart/National Medical Specialty Would Not Meet Its Purchase Commitment to SDG and that SDG Would Terminate Its Existing Contract With Stuart/National Medical Specialty

106. Prior to its merger with the Danek Group, Sofamor sold its CD and CCD Systems in the U.S. exclusively through an independent distributor, Stuart Medical, Inc. In 1993, Stuart Medical spun off that division of its business which sold the Sofamor products to NMS. After the merger between Danek Group and Sofamor, SDG became the owner of the CD and CCD Systems, although,

pursuant to a contract which ran through 1997, NMS continued to be the exclusive U.S. distributor of those products. In 1993, the CD and CCD Systems jointly accounted for 34% of SDG's consolidated sales.

107. As described above, defendants first publicly acknowledged that there was any problem between SDG and NMS on April 21, 1994. On that date, SDG reported that it had just been notified that Stuart/NMS would not meet its second quarter 1994 purchase commitment. While the April 21 disclosure of NMS's anticipated breach of its purchase commitment had a negative impact on SDG's stock price, defendants had known about the likelihood of this happening well before that time. Moreover, defendants also knew well before the end of the Class Period that SDG would likely terminate NMS's distribution contract (and purchase NMS's Sofamor product inventory).

108. Defendants, almost from the time of the merger between Sofamor and the Danek Group, had sought a means to terminate Stuart/NMS's exclusive distribution contract. To achieve this end, SDG, beginning in 1994, set virtually unattainable purchasing quotas for NMS — quotas which defendants knew NMS could not meet and still stay economically viable.

109. In fact, in February, 1994, NMS contacted SDG and informed SDG that NMS would probably not meet its second quarter purchase commitment. The fact that NMS

would not meets its purchase commitment for second quarter 1994 was confirmed by NMS to SDG in writing in March, 1994.

110. Defendants waited until April 21, 1994 to announce NMS's inevitable breach of its purchase commitment and the middle of June 1994 to announce what defendants had been planning for some time — the termination of NMS's distribution rights, the purchase of NMS's Sofamor products inventory and the start of SDG's direct sale of Sofamor products.

111. SDG's financials (and stock price) were negatively impacted by the NMS sales problems and termination of the NMS contract. SDG's second quarter 1994 sales fell 5.5 percent in the quarter to $38.1 million from $40.3 million in the same quarter in 1993. SDG also took a charge of $8.75 million against second quarter earnings in connection with termination of the NMS contract.

COUNT I
SECTIONS 10(b) AND 20(a) OF THE EXCHANGE ACT AND RULE 10b-5 OF THE SECURITIES EXCHANGE COMMISSION

112. Plaintiffs incorporate by reference and reallege paragraphs 1 through 111 above.

113. This Count is asserted against all defendants and is based upon Section 10(b) and 20(a) of the Exchange Act,

15 U.S.C. § 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the Securities and Exchange Commission.

114. During the Class Period, SDG and the individual defendants, singly and in concert, engaged in a plan, scheme and unlawful course of conduct, pursuant to which they knowingly and recklessly engaged in acts, transactions, practices, and courses of business which operated as a fraud and deceit upon plaintiffs and other members of the Class, and made various deceptive and untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading to plaintiffs and other Class members. The purpose and effect of the scheme was to induce plaintiffs and the Class to purchase SDG common stock during the Class Period at artificially inflated prices.

115. Defendants, pursuant to the plan, scheme and unlawful course of conduct, knowingly and recklessly issued, caused to be issued, participated in the issuance of deceptive and materially false and misleading statements to the investing public which were contained in or omitted from various documents, including documents filed with the SEC, and various other statements, as particularized above.

116. Each of the defendants knew or recklessly disregarded the fact that the acts and practices, misleading statements, and omissions described above would adversely affect the integrity of the market in SDG common stock

and/or artificially inflate or maintain the price of such stock. Had the adverse facts defendants concealed been disclosed, SDG stock would not have sold at the artificially inflated prices at which it sold during the Class Period.

117. In addition to the facts detailed in paragraphs 71-111 above, defendants' scienter can be inferred from their sale of SDG common stock during the Class Period. As described in paragraphs 13-20 above, by selling SDG stock without disclosing the material adverse non-public information of which they possessed, defendants were able to reap proceeds of over $24 million. Moreover, evidence of widespread knowledge throughout SDG and the former Sofamor of material adverse non-public information is evident from the tremendous sales of SDG common stock by other corporate insiders who are not named herein as defendants. These sales included:

Date of Sale	Number of Shares	Sale Price	Gross Receipt (exclusive of commissions)
Mark J. Merrill (Treasurer and Assistant Secretary, SDG)			
11/1/93	4,000	$32.94	$ 131,760.00
Sub-Total	4,000		$ 131,760.00

Annie Cotrel			
11/15/93	560	$31.00	$ 17,360.00
11/18/93	23,519	$30.08	$ 707,451.52
2/18/94	16,904	$34.01	$ 574,905.04
2/23/94	2,701	$33.00	$ 89,133.00
Sub-Total	43,684		$ 1,388,849.50
Yves Regis Cotrel			
11/15/93	560	$31.00	$ 17,360.00
11/18/93	23,519	$30.08	$ 707,451.52
Sub-Total	24,079		$ 724,811.52
Elisabeth Cotrel Gauzan			
11/15/93	560	$31.00	$ 17,360.00
11/18/93	23,519	$30.08	$ 707,451.52
2/23/94	4,125	$33.00	$ 136,125.00
Sub-Total	28,204		$ 860,936.52
Catherine Cotrel Lechein			
11/15/93	560	$31.00	$ 17,360.00
11/18/93	23,519	$30.08	$ 707,451.52
2/23/94	4,125	$33.00	$ 136,125.00
Sub-Total	28,204		$ 860,936.52

Marie Christine Cotrel Milliez

11/15/93	560	$31.00	$ 17,360.00
11/18/93	23,519	$30.08	$ 707,451.52
2/23/94	4,125	$33.00	$ 136,125.00
Sub-Total	28,204		$ 860,936.52

Benedicte Cotrel Sandere

11/15/93	560	$31.00	$ 17,360.00
11/18/93	23,519	$30.08	$ 707,451.52
2/18/94	16,904	$34.01	$ 574,905.04
2/23/94	2,701	$33.00	$ 89,133.00
Sub-Total	43,684		$ 1,388,849.50

Marie Helene Cotrel Plais (President, Sofamore S.N.C.)

11/15/93	560	$31.00	$ 17,360.00
11/18/93	23,519	$30.08	$ 707,451.52
2/18/94	11,269	$34.01	$ 383,258.69
2/23/94	1,801	$33.00	$ 59,433.00
Sub-Total	37,149		$ 2,267,503.20

Gerard Legall (Executive President, Sofamor S.N.C.)

11/18/93	1,557	$30.08	$ 46,834.56
2/18/94	1,409	$34.01	$ 47,920.09
2/23/94	225	$33.00	$ 7,425.00
Sub-Total	3,191		$ 102,179.65

Richard E. Duerr, Jr. (Vice President, General Counsel and Secretary, SDG)				
11/19/93	1,500	$30.00	$	45,000.00
Sub-Total	1,500	$30.00	$	45,000.00
Alexis V. Lukianov (President, Danek Medical, U.S.)				
11/19/93	9,698	$30.00	$	290,940.00
11/19/93	7,998	$30.00	$	239,940.00
Sub-Total	17,696		$	530,880.00
TOTAL OF ALL NON-DEFENDANT INSIDER TRADING	**259,595**		**$**	**9,162,642.93**

118. By reason of the foregoing, defendants, directly and indirectly, violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder in that they (a) employed devices, schemes and artifices to defraud, (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon plaintiffs and other members of the Class in connection with their

purchases of SDG common stock during the Class Period.

119. As a result of the foregoing, the market price of SDG common stock was artificially inflated during the Class Period. SDG Common stock traded as high as $41 per share during the Class Period and fell to $15 7/8 after disclosures on April 21, 1994, and to $12 3/4 on April 22, 1994. The ignorance of the false and misleading nature of the representations described above, plaintiffs and other members of the Class relied, to their detriment, on the integrity of the market as to the price of SDG common stock. The stock was traded in an open and efficient market. Among the factors which support the conclusion of an efficient market are that:

(a) the stock was constantly followed by and reported on by a significant number of securities analysts during the Class Period;

(b) millions of shares traded during the Class Period; and

(c) there existed a cause and effect relationship between unexpected corporate disclosures and an immediate response in the stock price, *e.g.*, Danek Group common stock jumped $4 1/8 on March 29, 1993 upon disclosure of the merger between Danek Group and Sofamor.

120. The price of SDG common stock declined materially upon public disclosure of facts which had been misrepresented or concealed as alleged in this Complaint. Plaintiffs and other members of the Class have suffered

substantial damages as a result of the wrongs herein allowed.

121. The individual defendants, by virtue of their offices, and/or directorships, had an exercised the power and influence to cause SDG to engage in the illegal conduct and practices complained of herein. As a result, at the time of the wrongs alleged herein, they were controlling persons of SDG within the meaning of Section 20(a) of the Exchange Act.

122. By reason of the conduct alleged herein, each individual defendant is liable under Section 10(b) of the Exchange Act pursuant to Section 20(a) thereof. As a direct and proximate result of the individual defendants' wrongful conduct, plaintiffs and members of the Class have been damaged in connection with their purchase of SDG common stock during the Class Period.

COUNT II
NEGLIGENT MISREPRESENTATION

123. Plaintiffs incorporate by reference and reallege paragraphs 1 through 122, as though fully set forth herein.

124. Since defendants are a public company and officers and directors of a public company, and because they issued documents to the investing public and made filings with the SEC, they owed a duty of due care to the plaintiffs and the Class in connection with financial statements, press releases and other reports they issued to the investing public regarding SDG. Defendants breached this duty knowingly or

recklessly or at least acted negligently by making various untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

125. At the time of such misrepresentations and omissions of material facts, plaintiffs were ignorant of their falsity and believed them to be true. Plaintiffs relied upon the superior knowledge and expertise of defendants and justifiably relied to their detriment on the misrepresentations and omissions of defendants to the market. Had the plaintiffs and the Class been aware of the true facts, they would not have purchased SDG common stock at all, or at the prices they paid.

126. Defendants' conduct constitutes negligent misrepresentation under applicable state common law. As a direct and proximate result of the negligent misrepresentations by defendants, plaintiffs and the Class suffered damages in connection with their purchases of SDG common stock.

COUNT III
COMMON LAW FRAUD AND DECEIT

127. Plaintiffs incorporate by reference and reallege paragraphs 1 through 126, as though fully set forth herein.

128. The misrepresentations and omissions by

defendants, as set forth above, constitute fraud and deceit under applicable state common law.

129. As a direct and proximate result of the fraud and deceit of defendants, plaintiffs and the Class suffered damages in connection with their purchases of SDG common stock.

JURY DEMAND

130. Plaintiffs demand a trial by jury on all issues.

WHEREFORE, plaintiffs on their own behalf and on behalf of the Class, pray for judgment, as follows:

A. Declaring this action to be a proper class action;

B. Awarding plaintiffs and all members of the Class damages in an amount which may be proven at trial, together with interest thereon;

C. Awarding plaintiffs their costs and expenses incurred in this action; including reasonable attorneys', accountants' and experts' fees;

D. Awarding punitive damages under Count III; and

E. Awarding such other and further relief as may be just and proper.

DATED: September 2, 1994

Respectfully submitted,

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Supreme Court, U.S.
FILED
APR 9 1998
CLERK

No. 97-1265

In the

Supreme Court of the United States

OCTOBER TERM, 1997

In re: SOFAMOR DANEK GROUP, INC.,

BRUCE G. MURPHY, RANDY OWEN,
MARY KENNEDY and LYNDA KRAMER

Petitioners,

- against -

SOFAMOR DANEK GROUP, INC., ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR
THE SIXTH CIRCUIT

RESPONDENTS' BRIEF IN OPPOSITION

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21 pp

QUESTIONS PRESENTED

1. Should a writ of certiorari be denied where Petitioners assert only fact-specific disputes or the misapplication of a properly stated rule of law in challenging the correctness of the opinions below, which dismissed this action on the ground that Sofamor Danek Group, Inc. ("SDG") accurately disclosed all material information concerning its financial status, including extensive disclosures in its public filings?

2. Does the precedent of *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) and *Chiarella v. United States*, 445 U.S. 222 (1980) demonstrate that, where a company's omissions under the federal securities laws are not material or plaintiffs fail to establish that the company has a duty to disclose the omitted information, the omissions — whether of specific promotional information or "hard" facts — are not actionable?

RULE 29.6 STATEMENT

Sofamor Danek Group, Inc. has no parent company. It has three nonwholly owned subsidiaries:

Danek Korea Co., Ltd.
Somepic Technologie S.A.
Kobayashi Sofamor Danek K.K.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
RULE 29.6 STATEMENT	ii
STATEMENT OF THE CASE	1
Overview	2
Petitioners' Claims and SDG's Disclosures	4
REASONS FOR DENYING THE WRIT	7
I. A writ of certiorari should be denied where, as here, Petitioners assert only fact-specific disputes or the misapplication of a properly stated rule of law in challenging the correctness of the dismissal of this action on the ground that Sofamor Danek Group, Inc. ("SDG") accurately disclosed all material information concerning its financial status, including extensive disclosures in its public filings.	7
II. The well-established precedent of *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) and *Chiarella v. United States*, 445 U.S. 222 (1980) demonstrates that, where a company's omissions under the federal securities laws are not material or plaintiffs fail to establish that the company has a duty to disclose the omitted information, the omissions — whether of specific promotional information or "hard" facts — are not actionable.	12
CONCLUSION	15

TABLE OF AUTHORITIES

Page

Cases:

Aschinger v. Columbus Showcase Co.,
934 F.2d 1402 (6th Cir. 1991) 8, 14

Basic Inc. v. Levinson, 485 U.S. 224 (1988) ..... i, 7, 8 9, 12

Chiarella v. United States, 445 U.S. 222 (1980) ..... i, 12, 14

Cortec Indus. v. Sum Holding L.P.,
949 F.2d 42 (2d Cir. 1991), *cert. denied*,
503 U.S. 960 (1992) 5

Femrite v. Abbott Northwestern Hosp.,
568 N.W. 2d 535 (Minn. Ct. App. 1997) 3

Howing Co. v. Nationwide Corp.,
826 F.2d 1470 (6th Cir. 1987),
cert. denied, 486 U.S. 1059 (1988) 14

Kramer v. Time Warner Inc.,
937 F.2d 767 (2d Cir. 1991) 5

Pompano-Windy City Partners v.
Bear Stearns & Co., 794 F. Supp.
1265 (S.D.N.Y. 1992) 5

Roeder v. Alpha Indus.,
814 F.2d 22 (1st Cir. 1987) 14

United States v. Algon Chem., Inc.,
879 F.2d 1154 (3d Cir. 1989) 3

United States v. Evers,
643 F.2d 1043 (5th Cir. 1981) 3

Page

Other Authorities:

15 U.S.C. § 78j(b) 5, 8

15 U.S.C. § 78t(a) 5

17 C.F.R. § 240.10b-5 (1997) 2, 5, 8, 9, 11

Supreme Court Rule 10 ..... 11, 12

Orthopedic Devices: Classification, Reclassification and Codification of Pedicle Screw Spinal Systems, 60 Fed. Reg. 51,946 (Oct. 4, 1995) 4

In the

Supreme Court of the United States

OCTOBER TERM, 1997

In re: SOFAMOR DANEK GROUP, INC.,

BRUCE G. MURPHY, RANDY OWEN,
MARY KENNEDY and LYNDA KRAMER

Petitioners,

- against -

SOFAMOR DANEK GROUP, INC., ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR
THE SIXTH CIRCUIT

RESPONDENTS' BRIEF IN OPPOSITION

STATEMENT OF THE CASE

Substituting overheated rhetoric for legal argument, Petitioners seriously mischaracterize the proceedings below. Their shareholder strike suit was properly dismissed with prejudice by the United States District Court for the Western District of Tennessee, and the dismissal was properly affirmed by the United States Court of Appeals for the Sixth Circuit. Both courts determined, in accordance with well-established and uncontroversial precedent, that Petitioners

failed to allege a single legally cognizable untrue statement or relevant omission under Rule 10b-5.

Overview

Sofamor Danek Group, Inc. ("SDG") is a publicly traded company incorporated in Indiana and headquartered in Memphis, Tennessee. Its principal focus is the development, preparation and distribution of prescription spinal fixation instrumentation systems throughout the United States and worldwide. These multiple-component products are used as "surgical splints" to stabilize the spine and promote successful fusion of vertebrae after spinal surgery.

This lawsuit was filed after SDG was named as a defendant in a series of product liability actions premised on the claim that SDG and other spinal implant manufacturers improperly promoted their products for off-label use in violation of FDA requirements. Petitioners copied the claims of the products liability plaintiffs and asserted that SDG's failure to admit in its public filings that it had in fact violated FDA regulations constituted securities fraud.

SDG has vigorously defended the products liability litigation. The company believes that it has complied with all applicable FDA regulations. SDG made substantial and complete disclosures concerning the status of its products with the FDA and concerning issues relating to the promotion of its products, the subject matter of plaintiffs' alleged "omissions" and "affirmative misrepresentations." Indeed, more than four years after the commencement of the products liability lawsuits and nationwide publicity concerning "pedicle fixation," and unprecedented efforts by the lawyers who aggregated the product claims, the FDA has not charged SDG with any improper action and no court has held that SDG violated in any way an FDA regulation. With the passage of time, it has become evident that the "disclosures" and "omissions" on which this suit is premised

are not only wrong, but had they been made would have been disastrous to the company's shareholders, who are purportedly represented by these Petitioners.

Each of SDG's spinal instrumentation systems has been cleared for promotion and sale by the FDA. *See* R. 28, Danek 1992 Form 10-K, dated March 29, 1993, p. 5; R. 28, Danek 1993 Form 10-K, dated March 30, 1994, pp. 6-7. Among the components in SDG's systems are screws which have been cleared by the FDA for certain uses. However, SDG may not promote these screws for other uses. Until early 1995, screws could not be labeled or promoted for use in the pedicles (bony support structures) of the cervical, thoracic or lumbar spine. SDG was permitted to promote the screws for use by a surgeon in the vertebral body via an anterior surgical approach and in the sacrum.

Many physicians utilize the screws for pedicle fixation. Under the "practice of medicine" exception, or "medical judgment" rule[1], SDG is legally permitted to sell its spinal fixation devices to physicians who may choose to employ

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[1] Petitioners' characterization of the "medical judgment" rule as an "apparent loophole," Petition at 7, is egregiously misleading. As courts have long recognized, the "medical judgment" rule constitutes long-standing FDA policy, which permits physicians to offer their patients state-of-the-art treatment. *See, e.g., United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981) (citing FDCA legislative history and FDA rulemaking interpreting the "practice of medicine" exception); *United States v. Algon Chem., Inc.*, 879 F.2d 1154, 1163 (3d Cir. 1989) ("Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses. Thus Congress exempted the practice of medicine from the [Food Drug and Cosmetic] Act so as not to limit a physician's ability to treat his patients") (citations omitted). *See also Femrite v. Abbott Northwestern Hosp.*, 568 N.W.2d 535, 541-42 (Minn. Ct. App. 1997) (after considering FDA documents, court concluded that physicians' implantation of bone screws in the vertebral pedicles "was a permissible 'off-label' use" not in violation of FDA regulations).

pedicle fixation techniques. However, FDA regulations restrict activities that the agency considers advertisement, labelling, promotion or marketing of devices for that purpose. Petitioners' complaint discloses that on July 22, 1994, an FDA advisory panel issued an unanimous recommendation which would permit manufacturer labelling and promotion of screws in the pedicle of the spine for certain medical indications. This recommendation was based on clear evidence of safety and efficacy. F-43-44, Complaint ¶ 95.[2]

Petitioners' Claims and SDG's Disclosures

Petitioners filed suit on April 25, 1994, purporting to represent a class of persons who purchased the common stock of SDG, or its predecessor Danek Group, Inc., from February 8, 1993 through and including April 21, 1994. F-10-11, Complaint ¶ 23. The essence of Petitioners' claims against SDG and the individual defendants[3] was that they had failed to disclose that the growth in revenues and profits was

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[2] After the filing of the complaint, SDG received approval for promotion of screws for use in the lumbar pedicles for a variety of medical indications. *See* Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems, 60 Fed. Reg. 51,946 (Oct. 4, 1995) (citing SDG's Section 510(k) application dated December 22, 1994). These FDA approvals included Section 510(k) clearance letters for SDG nonanterior hook and rod or plate and screw spinal instrumentation systems, received on the following dates: January 20, 1995 (TSRH system); August 7, 1995 (TSRH system); August 14, 1995 (Dyna Lok system); August 25, 1995 (Paragon system); August 28, 1995 (GDLH system); October 30, 1995 (Dyna Lok system); January 30, 1996 (TSRH and GDLH systems); February 9, 1996 (CD Liberty system); February 14, 1996 (Augment-T and CD Horizon systems); October 1, 1996 (CD system); December 5, 1996 (CD Horizon system); January 14, 1997 (Alpha system); February 6, 1997 (Titanium CD Horizon system); April 21, 1997 (Liberty system); and October 16, 1997 (CD system).

[3] The individual defendants, present or former officers and directors of Sofamor, Danek or SDG, include E. Ron Pickard ("Pickard"), Laurence Y. Fairey ("Fairey"), Leander D. Beard ("Beard"), George F. Rapp ("Rapp"), Miles D. Igo ("Igo"), and Alan J. Olsen ("Olsen").

based on illegal promotion of their products. The complaint alleges that the defendants violated sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a) (the "1934 Act"), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5 (1997), F-50-57, Complaint ¶¶ 112-122; that they negligently misrepresented certain facts, F-57-58, Complaint ¶¶ 123-126; and that they committed common law fraud and deceit, F-58-59, Complaint ¶¶ 127-129.

The district court correctly held that SDG had no duty to disclose, by way of predicting future FDA enforcement action or by pejoratively characterizing facts, what Petitioners claim was omitted from its Securities and Exchange Commission ("SEC") filings. In making this determination, the court quite properly examined SDG's public filings, which amply demonstrate that the company disclosed all of the information concerning its marketing practices and regulatory status that was required by the securities laws. The complaint itself, in contrast, indulged in selective quotation and lengthy mischaracterization of SDG's public filings[4].

The public filings show that SDG and its predecessor Danek Group, Inc. ("Danek") repeatedly made full disclosure of the regulatory status of its products. They specifically indicated the potential uncertainties associated with that status, including present and potential impacts on SDG's

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[4] Petitioners do not disagree that a court may properly consider on a motion to dismiss the full text of SEC filings mentioned in the complaint. Indeed, SDG was entitled to have a court consider the SEC filings under at least four theories, including: **(i)** public disclosure documents filed with the SEC, *see, e.g., Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991); **(ii)** documents integral to plaintiffs' claims, *see, e.g., Cortec Indus. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991), *cert. denied*, 503 U.S. 960 (1992); **(iii)** documents of which the court can take judicial notice, *see, e.g., Kramer*, 937 F.2d at 773; and **(iv)** incorporation by reference, *see, e.g., Pompano-Windy City Partners v. Bear Stearns & Co.*, 794 F. Supp. 1265, 1281 (S.D.N.Y. 1992).

promotional activities. In fact, Danek disclosed that its products were not cleared or approved for use in the pedicle area of the spine in public filings as early as May 16, 1991 — well over one year before the putative class period began and before the putative class plaintiffs purchased their shares. *See* R. 28, Danek Prospectus, dated May 16, 1991. Time and again, SDG both explained the scope and limitations of its FDA labelling approvals, and disclosed that its products were not approved for pedicular fixation labelling, but that many physicians used them for this "off label" indication, as is clearly authorized under the FDA's "practice of medicine" doctrine. SDG disclosed in detail the FDA's expressed concerns regarding improper promotion, and advised the market that were the FDA to pursue the company for any promotional violations, there would likely be adverse material effects on SDG's business.

The district court's October 3, 1995 order properly disposed of a legally deficient shareholder strike suit. It was entirely in accord with well-established legal precedent, and was affirmed by the Sixth Circuit on August 14, 1997. On October 9, 1997, after determining that the relevant issues had been "fully considered upon the original submission and decision of the case," the Sixth Circuit denied Petitioners' Petition for Rehearing and Suggestion for Rehearing *En Banc*. B-2.

Petitioners now claim, erroneously, that the lower courts "failed to in any way address the Petitioners-Plaintiffs' affirmative misrepresentation claim," Petition at 4. This "affirmative misrepresentation" claim, which is repeatedly belied by SDG's public filings, consists of two points: "First, that SDG publicly and affirmatively misrepresented to its investors and the market in general that it was not engaged in conduct or activities geared to promoting its [spinal instrumentation systems] for unapproved uses (*e.g.*, for pedicular attachment). Second, that given SDG's several and

undeniable promotional activities... these public and affirmative misrepresentations were *patently untrue*." Petition at 13. Petitioners also argue, incorrectly, that the lower courts "confused the question of whether it was necessary to disclose the material information regarding certain of the Company's activities, with the question of whether the disclosure needed to express the information in pejorative terms or to explicitly predict the potential ramifications of those activities." Petition at 5. They claim that SDG incurred a duty to disclose once it "directly addressed the issue of its promotional activities," Petition at 14, and that "the specific, concrete promotional activities SDG engaged in are facts that are at least as 'hard' as the merger negotiations activity at issue in *Basic, Inc. v. Levinson*, 485 U.S. 224 (1988)," Petition at 15.

REASONS FOR DENYING THE WRIT

I. A writ of certiorari should be denied where, as here, Petitioners assert only fact-specific disputes or the misapplication of a properly stated rule of law in challenging the correctness of the dismissal of this action on the ground that Sofamor Danek Group, Inc. ("SDG") accurately disclosed all material information concerning its financial status, including extensive disclosures in its public filings.

Petitioners argue erroneously that the courts below "simply ignored" their claim based on purported "affirmative misrepresentations." Petition at 12. Petitioners' point is inaccurate, and a similar argument was rejected by the Sixth Circuit in denying Petitioners' request for a rehearing *en banc*, *see* E-1, E-3-9. As the record makes clear, Petitioners'

argument concerning "affirmative misrepresentations" in no way implicates issues that warrant the granting of a writ of certiorari.

The lower courts' rulings on this matter are fully in accord with *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) and *Aschinger v. Columbus Showcase Co.*, 934 F.2d 1402 (6th Cir. 1991), which recognize that under § 10(b) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder, a claim may be grounded upon an affirmative misrepresentation. As *Basic* teaches, issues of materiality are particularly case and fact specific. 485 U.S. at 238-41. The lower courts' holdings were not only well-grounded in the facts pleaded in the complaint or supplemented by the company's SEC filings, but created no conflict, far less a "direct" one, with Supreme Court or Sixth Circuit precedent.

Petitioners' principal claim in this action is that SDG committed securities fraud, by failing to disclose purported violations of FDA regulations. However, Petitioners' allegations — as the district court correctly determined when dismissing the complaint with prejudice, and as the Sixth Circuit correctly affirmed — fail to support a cause of action under the federal securities laws.

The Sixth Circuit's opinion uncontroversially interprets *Basic* and *Aschinger* as follows:

> To state a cause of action under §10(b) and Rule 10b-5 a plaintiff must plead that the defendant made a false statement or omitted to state a material fact which should have been disclosed, and that the plaintiff's reasonable reliance on the statement or omission proximately caused the plaintiff's injury. *See Aschinger v. Columbus Showcase Co.*, 934 F.2d 1402, 1409 (6th Cir. 1991). Misrepresented or omitted facts are material only if a reasonable

> investor would have viewed the misrepresentation or omission as "having significantly altered the total mix of information available." *Basic, Inc. v. Levinson*, 485 U.S. 224, 232 (1988) (internal quotation marks and citation omitted).

A-15-16 (citations omitted).

Moreover, the Sixth Circuit accurately noted, "Before liability for non-disclosure can attach, the defendant must have violated an affirmative duty of disclosure. *See Basic*, 485 U.S. at 239 n.17 ('Silence, absent a duty to disclose, is not misleading under Rule 10b-5'). Ordinarily, at least, a company is under no duty to disclose the details of its merchandising practices... Materiality alone is not sufficient to place a company under a duty of disclosure." A-16 (citations omitted).

Petitioners argue that the lower courts overlooked their claim for violation of the federal securities laws based on SDG's purportedly untrue "affirmative representations" that it "was not engaged in conduct or activities geared to promoting" its products for "unapproved uses (*e.g.*, for pedicular attachment)." *See* Petition at 13. In effect, this is just a rehash of their claim that SDG promoted its products in violation of FDA regulations. The Sixth Circuit considered at length all of plaintiffs' claims about affirmative misstatements and omissions concerning SDG's promotional practices, and correctly disposed of this claim after examining closely the relevant SEC filings. *See* A-6-7 (describing SDG's disclosures in its public filings concerning pedicular attachment, including SDG's disclosure of an August 1993 FDA warning letter concerning the practice); A-12-13 (detailed summary of plaintiffs' allegations that "the market was unaware that the company was improperly promoting its products for pedicular use"); A-14-17 (analysis of those allegations in light of

governing law, including *Basic*, with conclusion that SDG did not violate federal securities laws).

The Sixth Circuit correctly held that the sales and earnings data publicly reported by SDG "are 'hard' numbers, the accuracy of which has never been challenged by the plaintiffs." A-19. The Sixth Circuit also observed, "Neither have the plaintiffs pointed to any affirmative misstatement in the company's explanations of the numbers." *Id.* Rather, SDG repeatedly disclosed all that was required of it under the federal securities laws, and "Each of the company's 10-K forms explicitly mentioned the risk that the FDA might obtain an injunction" against distribution of its products. *Id.* at A-21.

The public filings show that SDG and its predecessor Danek repeatedly made full disclosure of the regulatory status of its products and its promotional activities. *See, e.g.*, R. 28, 1993 Danek Proxy Statement, at 61 (disclosing that "medical education, physician training and developing personal relations with surgeons are the integral components" to marketing strategy).

At least four Danek public filings disclosed that the screw components of Danek's product line were not FDA cleared or approved for pedicle use; that many surgeons legally use these screws in the pedicle; that the FDA might take action in the future that would affect such use; that the FDA was investigating improper promotional activities; and that FDA action could have a material adverse impact on Danek's business and financial conditions. *See* R. 28, Danek Prospectus, dated May 16, 1991; R. 28, 1992 Form 10-K; R. 28, 1993 Form 10-K; A-20. As the Sixth Circuit opinion recites, "In August of 1993, as the company disclosed in its Form 10-K for that year, 'Danek and six other companies received warning letters from the FDA, primarily regarding the issue of supporting medical education programs that

actually 'demonstrate' the use of screws in the pedicle of the spine'." A-8.

Thus, SDG disclosed all that was required by the federal securities laws concerning its marketing practices and regulatory status, and in making those disclosures, it asserted nothing that could be legally or logically construed as an "affirmative false statement." The Sixth Circuit concluded that no more was required of SDG under the federal securities laws. That conclusion is well reasoned and fully in accord with Supreme Court and Sixth Circuit precedent on the duty of disclosure, including *Basic* and *Aschinger*.

The Sixth Circuit's opinion with respect to the adequacy and accuracy of SDG's disclosures was solidly grounded upon the reasoning of the trial court. As that court stated, to be actionable under the securities laws, a complaint must point to some affirmative statement that was false or misleading when made or as to which prompt correction was "'necessary to make' that affirmative statement 'not misleading.'" C-14; 17 C.F.R. § 240.10b-5 (1997). After examining the full documents that were selectively quoted by plaintiffs, the trial court properly found that none of SDG's affirmative statements were actionable. C-21.

In sum, Petitioners complain not so much that the lower courts departed from established precedent, but rather that the facts of this case should have led to a different result. Petitioners' argument falls squarely within the Court's guidance that, "A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." Supreme Court Rule 10. Whether or not SDG should have disclosed additional facts about how it marketed its products does not involve issues of precedent-setting importance, and Petitioners fail to show "compelling reasons," *id.*, to support such a grant.

II. The well-established precedent of *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) and *Chiarella v. United States*, 445 U.S. 222 (1980) demonstrates that, where a company's omissions under the federal securities laws are not material or plaintiffs fail to establish that the company has a duty to disclose the omitted information, the omissions — whether of specific promotional information or "hard" facts — are not actionable.

Petitioners argue, in addition, that the lower courts "erred in their application of the relevant law" in determining that SDG had no duty to disclose further information about its promotional activities. Petition at 14. Specifically, Petitioners claim that SDG was required to disclose more about its activities once it "took it upon itself to speak at all," Petition at 15, and that SDG was required to disclose such matters because they constituted "cold, *hard* facts" concerning purportedly material activities. Petition at 15-16.

This argument also fails utterly to warrant the Court's granting of the Petition. Not only is a petition for a writ of certiorari "rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law," Supreme Court Rule 10, but both lower courts were plainly correct in their application of the relevant law.

Indeed, with respect to this point, both the Sixth Circuit and the district court followed the governing standard that has long been established by this Court under *Basic*.[5]

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[5] The Sixth Circuit noted, "We find ourselves in substantial agreement with the district court's analysis," A-3, and indicated that its ruling was "for substantially all of the reasons given by Judge Turner," A-28.

Contrary to plaintiffs' assertions, additional information about specific promotional activities and "hard" facts is neither material nor subject to required disclosure under the *Basic* standard. The district court opinion noted, "[i]nvestors, of course, would like to have any material information, but they are not entitled to all information that might somehow be of assistance to them in predicting the future of the stock." C-16. That court cites *Basic* and *Chiarella* for the well-established proposition that omissions are only actionable where defendants have a "duty to disclose" the information at issue. C-17. However, contrary to *Basic*, the Petition now argues for what is really "all information that might somehow be of assistance" to shareholders, as distinct from material information that is required to be disclosed. C-16.

The courts below did not determine that any of SDG's purported omissions were material, but held that even if they were, plaintiffs had failed to satisfy the "duty to disclose" requirement which is a prerequisite to any securities fraud claim. That reasoning applies equally to the "specific" and "hard fact" categories of information cited in the Petition. With respect to all of SDG's alleged omissions, the admittedly true statements made and reports filed by SDG cannot be shown to have been misleading by reason of SDG's failure to disclose the areas of information alleged in the Complaint to be missing. C-28-29. There is simply no such duty under the federal securities laws.

The district court and the Sixth Circuit both held that, even if materiality is established, a duty to disclose the information arises only under specific circumstances, namely: **(i)** where a corporate insider uses material non-public information to profit financially in the securities markets; **(ii)** where a company omits material information in a report it must file pursuant to a particular statute or regulation; or **(iii)** where defendants have made a public statement, and further disclosures are necessary to make the statement not

misleading. C-18 (citing *Chiarella*, 445 U.S. at 226-30; *Roeder v. Alpha Indus.*, 814 F.2d 22, 26-27 (1st Cir. 1987); *Howing Co. v. Nationwide Corp.*, 826 F.2d 1470, 1481 (6th Cir. 1987), *cert. denied*, 486 U.S. 1059 (1988)); Opinion at 11-12. Petitioners have failed to demonstrate that any of these circumstances apply to SDG's purported omissions, and have therefore failed to establish any claim against SDG under the federal securities laws.

For all of these reasons, the Sixth Circuit's affirmation of the district court's dismissal properly disposed of a legally deficient shareholder strike suit. Both opinions are uncontroversial and fully in accordance with existing Supreme Court and Sixth Circuit precedent, including *Basic* and *Aschinger*.[6] In no way do the perfunctory, fact-specific arguments set forth in the Petition warrant this Court's utilization of its resources in further reviewing Petitioners' groundless claims.

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[6] Notably, Petitioners, who discuss *Aschinger* at length in their Sixth Circuit Petition for Rehearing and Suggestion for Rehearing *En Banc*, E-1 *et seq.*, do not even attempt to argue to this Court that the Sixth Circuit's present opinion conflicts with the precedent set forth in *Aschinger*.

CONCLUSION

For all of the foregoing reasons, SDG respectfully requests that this Court deny the Petition for a Writ of Certiorari.

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Respectfully submitted,

/s/

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